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No. OFFICE OF THE CLERK

**In the
Supreme Court of the United States**

JOHN PARKER ROE,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

**On Petition for a Writ of Certiorari to the United
States Court of Appeals for the Sixth Circuit**

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Whether the Defendant was denied the effective assistance of counsel and due process of law by the actions of trial counsel without the Defendants approval, the refuse to permit him to be evaluated and thereby eliminating his only defense. There is a reasonable probability that the result as to first degree murder would have been different had counsel not been ineffective.

Was the Defendant denied counsel and a fair jury by the action of counsel, over the objection of the Defendant, permitting his jailer to serve on his jury.

RULE 14.1(b) STATEMENT

The Petitioner/Appellant: John Parker Roe.

Respondent/Appellee: United States of America

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PETITION FOR A WRIT OF CERTIORARI

Petitioner John Parker Roe respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit in this case.

OPINIONS BELOW

The opinion for the Court of Appeals (is attached as Appendix A).

JURISDICTION

The judgment of the Court of Appeals was entered on July 11, 2005. This Court's jurisdiction is invoked under 28 U.S.C. § 2241 & 28 U.S.C. § 2254.

STATUTORY AND REGULATORY PROVISIONS INVOLVED

28 U.S.C. § 2254 governs Petitions to vacate State Judgments heard in the Federal Courts.

STATEMENT

The District Court and Court of Appeals bellowed denied a Motion for Certificate of Appealability.

REASON FOR GRANTING PETITION

In recent years this Court has zealously enforced one of our most important constitutional rights – the Right to a Trial by Jury. In the line of cases beginning with *Apprendi v. New Jersey*, 530 US 466, 120 S. Ct. 2348, 147 L. Ed. 2d 435 (1999) and ending with *Blakely v. Washington*, 124 S. Ct.

1493, 158 L. Ed. 75 and *US v. Booker*, ___ US ___, 125 S. Ct. 738, ___ L. Ed. 2d ___ (2005) this Court recognized that a fair jury should be required to decide any issues of fact. In this case, the Defendant was put to trial over his personal objection with a jury which included one of his jailers. Such allowance by the Court and Defense Counsel certainly denied the Defendant due process of law and the effective assistance of counsel. And very importantly, it denied him the right to have a fair jury try his case.

In addition, the Petitioner would ask this Court to grant Certiorari because Counsel was so deficient in this case as to essentially be no counsel under *Cronic v. United States*, 466 US 648, 104 S. Ct. 239, 80 L. Ed. 2d 657 (1984). To deprive the Defendant, over his objection, of the only defense available to him is to effectively eliminate counsel. Trial Counsel, over the objection of the Defendant, instructed him not to participate in a State Ordered mental evaluation, thereby preventing him from raising his claim of diminished capacity.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT**

No. 04-6445

[Filed July 11, 2005]

<u>JOHN PARKER ROE,</u>)
Petitioner-Appellant,)
)
v.)
)
JACK MORGAN, Warden,)
Respondent-Appellee.)
<u></u>)

ORDER

John Parker Roe, a Tennessee state prisoner, moves through counsel for a certificate of appealability, and appeals a district court judgment denying his petition for a writ of habeas corpus, filed under 28 U.S.C. § 2254.

Upon consideration, the motion for a certificate of appealability is denied.

ENTERED BY ORDER OF THE COURT

/s/ Leonard Green
Clerk

APPENDIX B

**UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

No. 03-2121

[Filed November 9, 2004]

JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
JACK MORGAN, Warden,)
Respondent.)

**ORDER OF DISMISSAL OF PETITION FOR WRIT
OF HABEAS CORPUS; ORDER DENYING
RESPONDENT'S MOTION TO STRIKE; AND
ORDER DENYING RESPONDENT'S MOTION FOR
JUDGMENT AS A MATTER OF LAW**

On February 28, 2003, John Parker Roe ("Roe") petitioned this court for a writ of habeas corpus under 28 U.S.C. § 2254. Roe is serving a life sentence at the Brushy Mountain Correctional Complex. On October 31, 2003, Jack Morgan ("Morgan"), warden of the Brushy Mountain Correctional Complex, filed a "Motion for Judgement as a Matter of Law." Also pending is Morgan's "Motion to

Strike" filed January 12, 2004. For the following reasons, Roe's petition is DISMISSED and all other pending motions are DENIED as moot.

I. Background

Roe was convicted of first-degree murder in the Criminal Court of Shelby County, Tennessee, on August 30, 1996. (Pet. at 1.) He appealed to the Tennessee Court of Criminal Appeals, which affirmed his conviction on January 12, 1998. (*Id.* at 3.) Roe sought leave to appeal to the Tennessee Supreme Court, which denied his application for permission to appeal on January 4, 1999. (*Id.*) He filed a petition for certiorari to the Supreme Court of the United States, which was denied on June 7, 1999. (*Id.* at 4.) Roe then sought post-conviction relief in the Criminal Court of Shelby County. (*Id.*) That court conducted an evidentiary hearing and denied Roe's claim on October 31, 2000. (*Id.* at 5.) Roe appealed. The Tennessee Court of Criminal Appeals affirmed the trial court's denial of post-conviction relief, and the Tennessee Supreme Court denied Roe's application for permission to appeal on February 24, 2003. *See Roe v. State*, 2002 WL 31624850 (Tenn. Crim. App. Nov. 20, 2002), *app. denied*, Feb. 24, 2003.

Roe filed the present 28 U.S.C. § 2254 petition for writ of habeas corpus on February of 28, 2003, seeking to vacate his conviction. On October 1, 2003, Roe filed with this court a "Notice of Supplemental New Scientific Evidence in Support of Motion to Vacate Judgment," in which he presented evidence that he had not presented to the state courts. On December 31, 2003, Roe filed a "Second Submission of Supplemental Factual Authority in Support of Petition to Vacate Tennessee Judgment Due to New Evidence," and, on January 2, 2004, he submitted a "Notice

of Filing/Submission of New Evidence" in support of his petition.

On October 31, 2003, respondent Morgan filed a "Motion for Judgment as a Matter of Law". On January 12, 2004, Morgan filed a "Motion to Strike [Roe's] Supplemental Filings and to Dismiss [Roe's] Petition Without Prejudice Pending Exhaustion." In that motion, Morgan stated that Roe had filed a motion to reopen his post-conviction petition in the Criminal Court of Shelby County on October 8, 2003, and had provided to the state court the same evidence he had provided to this court in his October 1, 2003, "Notice of Supplemental New Scientific Evidence in Support of Motion to Vacate Judgment." (Mot. to Strike at 1 and Attachment 1.) The trial court denied his motion to reopen, and Roe filed a notice of appeal on December 8, 2003. (*Id.* Attachments 2 and 3.) Morgan therefore moved the court to dismiss Roe's petition without prejudice because Roe was pursuing a state court motion to reopen his post-conviction petition involving one of the issues he sought to raise in his federal petition. (Mot. to Strike at 2.) On March 26, 2004, this court issued an "Order Staying Case" pending resolution of the state trial court's denial of his motion to reopen. On September 22, 2004, Roe submitted a "Notice of Exhaustion of State Remedies" and this court responded six days later by issuing an "Order Reopening Case."

Before the court now are 1) Roe's petition for writ of habeas corpus, in which Roe contends that his conviction is unlawful and should be vacated due to constitutional violations at his trial; and 2) Morgan's motion for judgment as a matter of law.

II. Facts

The Tennessee Court of Criminal Appeals, in its order denying Roe's petition for post-conviction relief, gave the factual background of the murder underlying this case:

The Defendant was a police officer with the Memphis Police Department. At about seven o'clock on the morning of September 16, 1994, the Defendant called fellow officer Carl Fowler and asked him to come to the Defendant's house. Mr. Fowler testified that the Defendant told him over the phone that Michelle, the Defendant's wife, had run off. When Fowler arrived about an hour later, he noticed that Michelle's car was there. Fowler asked the Defendant where Michelle was, and the Defendant replied, "It's worse than you think." The Defendant then told Fowler that he had shot Michelle and that she was in "the bottoms" an area of scrubland behind the Defendant's house. The Defendant told Fowler that he and Michelle had been hunting rabbits, and that he accidentally shot her in the head with his service revolver. When Fowler told the Defendant that they needed to call the police, the Defendant adamantly refused.

Mr. Fowler was a good friend of the Defendant and had spent considerable time with him, both on and off the job. Fowler testified that he "thought [he] knew [the Defendant] very well, and the person [he] ran into that day was not the John [he'd] ever met." Fowler explained that he had smelled an odor of alcohol on the Defendant. Fowler testified that, in his opinion, the Defendant was "mentally ill" that morning, and explained that earlier that week, the Defendant had told him that he had heard voices coming out of the

heating vent. Fowler described the Defendant's behavior on the morning in question as "weird" and "strange." Convinced that the Defendant could not control his own behavior, Mr. Fowler became fearful for his own life and left.

Mr. Fowler flagged down Deputy William Hughes with the Shelby County Sheriff's Department and told him about the shooting. When Deputy Hughes arrived at the Defendant's house, he found the Defendant sitting on the tailgate of his truck drinking a beverage. Hughes asked the Defendant where his wife was, and the Defendant replied, "[S]he could be anywhere." Hughes noticed that the Defendant was perspiring very heavily.

Officer Anthony Chambers arrived as back-up and entered the Defendant's house. There he found Michelle's body lying on the bed. She had been shot in the head and a towel was draped over the wound. Hughes subsequently arrested the Defendant who, according to Hughes, appeared "[v]ery calm." The Defendant's profuse sweating concerned Hughes, however, and Hughes asked a paramedic to check his vital signs. Paramedic Randall Wayne Rhodes testified that the Defendant's heart rate and respiration were higher than normal, and that he appeared disoriented, or "spaced out." The Defendant denied having taken any drugs and told Rhodes that he had been under a lot of stress.

Sergeant F.B. Roberts arrived on the scene and spoke with the Defendant as he sat in the squad car. Roberts testified that the Defendant "seemed very confused" and never told him what had happened. He described

the Defendant's conversation as "irrational." In the house, Roberts found an empty bottle of whiskey and four bottles of an over-the-counter drug called "Mini-Thins" in the trash. Other bottles of Mini-Thins containing pills were found throughout the house.

Larry Graham, a long time friend of the Defendant, visited the Defendant while he was in jail. There, the Defendant told Mr. Graham both that the killing had been accidental and that he didn't know/remember what had happened. Graham stated that the Defendant had appeared "glaze-eyed," and "wasn't the person that [he] knew."

Daniel Kaltreider testified that he met the Defendant through his cousin, John Barnette. Mr. Kaltreider attended a bar-b-cue in the spring of 1994 that the Defendant and Michelle also attended. There, he testified, the Defendant told him "that he had a tremendous amount of rage at his wife," and that he was going to kill her. Kaltreider testified that the Defendant asked him if he thought the Defendant could "get away with it" if the Defendant "said it was an accidental discharge." When Kaltreider replied no, because he would have to testify against the Defendant, the Defendant stated, "Then I'll have to kill you." The conversation continued, according to Kaltreider, with the Defendant stating, "Well, I'll just have to play crazy for about seven--six months."

John Barnette had known the Defendant several years and testified that the Defendant's marriage with Michelle was "rocky." He stated that the Defendant had told him that the Defendant wanted to divorce Michelle and also spoke of wanting to kill her. The

Defendant told him that he had choked Michelle at one point and thought about killing her then.

On cross-examination, Mr. Barnette testified about the massive amounts of Mini-Thins that the Defendant was taking in 1994. Barnette testified that he saw the Defendant taking ten to fifteen of these tablets at a time. He explained that these pills, combined with the Defendant's drinking, caused the Defendant to develop a Dr. Jekyll/Mr. Hyde personality. Barnette testified that the Defendant spoke to him about hearing voices and seeing ghosts. The Defendant became very paranoid and suspicious about Michelle. During the summer of 1994, Barnette testified, the Defendant's conversations became incoherent, irrational, and "bizarre." Barnette described the Defendant as "out of his head" and testified that he became "deeply concerned" about the Defendant because of his increasingly irrational behavior.

Peter Connelly was one of Michelle's teachers at the college which Michelle attended. Mr. Connelly testified that, two days before her death, Michelle told him that the Defendant had abused her and threatened to kill her. She wrote down her parents' phone number and asked Connelly to call them if she did not show up for her next class. When Michelle failed to attend her next class on the morning of her death, Connelly called her parents. Michelle's mother subsequently went to the Defendant's house, arriving while Officer Fowler was there.

Expert testimony established that Michelle was killed by a single gunshot to her head, fired from twelve to

twenty-four inches away. The bullet was fired from the Defendant's police service revolver.

Dr. O'Brian Cleary Smith, who performed the autopsy on Michelle, was asked on cross-examination about ephedrine, the active ingredient in Mini-Thins. Dr. Smith testified that, when taken fifteen tablets at a time, "it has the same effect as an overdose of amphetamine. It can be an irritant to the heart and set up cardiac arrhythmia--in other words, irregular heartbeat. It can also be very stimulating to the central nervous system of the brain causing the person to act in an irrational manner, to have hallucinations or to see things or feel things that aren't there."

Elton Douglas, one of the Defendant's jailers, testified on behalf of the Defendant. He explained that the Defendant was on suicide watch for five days after his arrest. During this time, the Defendant was confused and engaged in incoherent mumbling, refusing regular conversation. When asked to compare the Defendant's behavior during his first month in jail to the several months preceding trial, Mr. Douglas stated, "[I]f I was to ask him a question [recently], he would answer it; where then, if I was talking to him, there was no reply or no thought process involved."

Clyde William Keenan of the Memphis Police Department also testified on behalf of the Defendant. He had supervised the Defendant for approximately two years. When called to the scene, he found the Defendant lying in the back of the squad car, "half way on the seat and half way into the floorboard." When the Defendant sat up, Keenan testified, he had a "wild look about him" and was sweating profusely.

The Defendant asked Keenan, "[W]hat's going on?" and stated, "[E]verything is breaking up." Keenan testified that he concluded at the time that the Defendant had "completely snapped" and was mentally ill. He told the sheriff's deputies at the scene that "[t]his young man is over the edge." He also testified that, at the time, the Defendant had not been capable of consenting to a DUI test.

Ted Hansom, the Defendant's first attorney, testified that he saw the Defendant when the officers initially brought him into the station. He stated that the Defendant was "unable to communicate," "not coherent," and "not oriented." He testified that the Defendant had been "unable to understand what was going on."

Roe, 2002 WL 31624850, at *3-6.

III. Legal Standard

The Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA), 28 U.S.C. § 2254(d), governs this case. Under the AEDPA, a writ of habeas corpus may issue only if the state court adjudication of an issue:

(1) resulted in a decision that was contrary to, or involved an unreasonable application of, clearly established Federal law, as determined by the Supreme Court of the United States; or

(2) resulted in a decision that was based on an unreasonable determination of the facts in light of the evidence presented in the State court proceeding.

28 U.S.C. § 2254 (d). All of Roe's claims include questions of federal law and are reviewed under the standard in 28 U.S.C. § 2254 (d) (1).

"A state court decision is 'contrary to' clearly established federal law 'if the state court applies a rule that contradicts the governing law set forth in [Supreme Court] cases,' or 'if the state court confronts a set of facts that are materially indistinguishable from a [Supreme Court] decision ... and nevertheless arrives at a result different precedent.'" *Bulls v. Jones*, 274 F.3d 329,333 (6th Cir. 2001) (quoting *Williams v. Taylor*, 529 U.S. 362, 405-05 (2000)).

"An 'unreasonable application' of clearly established federal law occurs when the state court identifies the correct governing legal rule from this Court's cases but unreasonably applies it to the facts of the particular state prisoner's case.'" *Bulls*, 274 F.3d at 333 (quoting *Williams*, 529 U.S. at 407). However, "the term 'unreasonable' is not synonymous with 'incorrect.' Therefore, 'a federal habeas court may not issue the writ simply because that court concludes in its independent judgment that the relevant state-court decision erroneously or incorrectly. Instead, the correct inquiry is 'whether the state court's application of clearly established federal law was objectively unreasonable.'" *Schoenberger v. Russell*, 290 F.3d 831, 834 (6th Cir. 2002) (quoting *Williams*, 529 U.S. at 410-411)

IV. Analysis

Roe's petition for a writ of habeas corpus contains six claims for relief. Each claim is reviewed as follows:

A. Ineffective Assistance of Trial Counsel

Roe argues that in four instances, his attorneys failed to provide effective assistance at trial. Because the State sought the death penalty in this case, Roe was represented at trial by two lawyers. Wayne Emmons was retained counsel and Edward Witt Chandler was appointed co-counsel. (Chandler Test., Hear. for Post-Conv. Rel. at 63:20-23.) The Criminal Court of Shelby County and the Tennessee Court of Criminal Appeals rejected Roe's claims of ineffective assistance of trial counsel. The test is whether the state trial and appellate courts' decisions are contrary to, or involved an unreasonable application of, the controlling United States Supreme Court case on this issue, *Strickland v. Washington*, 466 U.S. 668 (1984).

Strickland established a two-part test for a claim that assistance of counsel was so ineffective as to be constitutionally deficient. "First, the defendant must show that counsel's performance was deficient. This requires showing that counsel made errors so serious that counsel was not functioning as the 'counsel, guaranteed the defendant by the Sixth Amendment. Second, the defendant must show that the deficient performance prejudiced the defense. This requires showing that counsel's errors were so serious as to deprive the defendant of a fair trial, a trial whose result is reliable." *Id.* at 687.

When reviewing trial counsel's performance for deficiency, the post-conviction court should afford a great deal of deference to the strategic decisions made by trial counsel:

Judicial scrutiny of counsel's performance must be highly deferential. It is all too tempting for a

defendant to second-guess counsel's assistance after conviction or adverse sentence, and it is all too easy for a court, examining counsel's defense after it has proved unsuccessful, to conclude that a particular act or omission of counsel was unreasonable. A fair assessment of attorney performance requires that every effort be made to eliminate the distorting effects of hindsight, to reconstruct the circumstances of counsel's challenged conduct, and to evaluate the conduct from counsel's perspective at the time. Because of the difficulties inherent in making the evaluation, a court must indulge a strong presumption that counsel's conduct falls within the wide range of reasonable professional assistance; that is, the defendant must overcome the presumption that, under the circumstances, the challenged action might be considered sound trial strategy.

Id. at 689 (internal quotes and citations omitted).

To satisfy the prejudice prong, a petitioner must show that "there is a reasonable probability that, but for counsel's unprofessional errors, the result of the proceeding would have been different. A reasonable probability is a probability sufficient to undermine confidence in the outcome." *Id.* at 694. In *Lockhart v. Fretwell*, 506 U.S. 364 (1993), the Supreme Court stated that "an analysis focusing solely on mere outcome determination, without attention to whether the result of the proceeding was fundamentally unfair or unreliable, is defective." *Id.* at 369; *See also McQueen v. Scroggy*, 99 F.3d 1302, 1311 (6th Cir. 1996) (finding that a reviewing court's investigation of prejudice should focus on whether counsel's alleged errors "have undermined the reliability of and confidence in the result").

1. Advice not to Submit to Psychological Exam by Court Appointed Psychiatrist

Roe's trial lawyers advised him not to submit to a psychological evaluation with Dr. Lynn Zager, the court appointed psychiatrist. *Roe*, 2002 WL 31624850, at *6. As a result, the trial court ruled that Roe could not present expert proof concerning his mental state at the time of the murder. *Id.* at *6. Specifically, Roe was not able to present the testimony of Dr. Jonathan Lipman, a Neuropharmacologist, who would have discussed the psychological effects of ephedrine use, and would have testified that Roe had "record high" levels of ephedrine in his system at the time he killed his wife. *Id.* at *6-7. Roe argues that the advice not to submit to the psychological exam constitutes ineffective assistance of trial counsel warranting a reversal of his conviction.

The Tennessee Court of Criminal Appeals described the testimony of Roe's trial lawyers at the post-conviction relief hearing as follows:

Mr. Chandler, one of the Defendant's two trial lawyers, testified that he advised the Defendant not to talk to Dr. Zager because he was convinced that she would testify that the Defendant had no mental illness or disease, that he knew what he was doing when he shot Michelle, and that he was able to control his behavior. One of the reasons for Mr. Chandler's decision was that Dr. Zager and the prosecutor were "big personal buddies," and he believed that Dr. Zager would find whatever the prosecutor wanted her to find with respect to the Defendant's mental state. Mr. Chandler explained that he knew Dr. Zager "from a number of cases" and felt that she was "extremely biased against defendants." Mr. Chandler testified that

Dr. Zager's anticipated testimony that the Defendant was sane would cause them to lose "the best defense [they had]" and "would knock out the defense." Mr. Chandler stated that he did not think that Dr. Lipman's testimony would overcome Dr. Zager's anticipated testimony, and for that reason, he decided that the better strategy was to argue to the trial judge at the close of the State's proof that the State did not carry its burden of proving the Defendant sane. Mr. Chandler testified that, in his experience, jurors do not like the insanity defense. Accordingly, he stated, he "was trying to win the case with the trial judge." Mr. Chandler stated that he "was absolutely convinced" that they were going to create an issue of sanity with their lay witnesses. In hindsight, Mr. Chandler admitted, his advice to the Defendant regarding Dr. Zager might have been a mistake. However, he also testified that "there wasn't any doubt in [his] mind at the time [they] were doing the right thing."

Mr. Emmons [Roe's other trial lawyer] also testified that the trial strategy was to put on sufficient lay proof of the Defendant's insanity to shift the burden of proving the Defendant's sanity to the State. He explained that they had three very strong lay witnesses with which to accomplish this goal.

At the close of the State's proof at the Defendant's trial, Mr. Chandler moved to acquit the Defendant of first degree premeditated murder on the grounds that the State had not adduced sufficient proof that the Defendant had killed Michelle with premeditation and deliberation, and on the grounds that the State had "failed to prove sanity sufficient enough to send the case to the jury." The trial court overruled the motion.

Id. at *7-8.

The Criminal Court of Shelby County denied Roe's petition for post-conviction relief on this issue and the Tennessee Court of Criminal Appeals affirmed the trial court's decision stating:

This Court has carefully reviewed the transcripts of both the trial and the post-conviction hearing. There is no doubt that the Defendant's trial lawyers provided him with reasonable and competent representation. There is also no doubt that the Defendant's trial lawyers deliberately chose a course of action which precluded their putting on the witness stand two very powerful expert witnesses. Defense counsel had a very difficult tactical decision to make about how best to present the Defendant's defense of insanity and evidence of his diminished capacity to form the required mens rea of premeditation and deliberation. In hindsight, Mr. Chandler admitted that perhaps they chose the wrong alternative. However, hindsight is not the proper lens through which to view a claim of ineffective assistance of counsel. The Defendant's trial lawyers made a strategic decision after a thorough investigation into the facts and legal theories, and after repeated pretrial efforts to maintain their defense while avoiding an evaluation by Dr. Zager. The fact that a particular strategy or tactic failed or hurt the defense, does not, standing alone, establish unreasonable representation. While the Defendant and his trial lawyers may wish that they had chosen a different course of action following the Defendant's conviction, this Court is not inclined to criticize strategic trial decisions made in conjunction with the level of legal skill brought to bear in this case. To do so would be

to call into question almost every strategic decision made on behalf of criminal defendants in this state. Post-conviction relief on the basis of ineffective assistance of counsel is aimed at addressing incompetent representation; not representation that simply fails to defeat the State's case. In short, the Defendant has failed to prove by clear and convincing evidence that his trial lawyers' performance fell below the standard of competence demanded by our constitutions.

Accordingly, this issue is without merit.

Id. at *8-9 (internal quotes and citations omitted).

The decisions of the Criminal Court of Shelby County and the Tennessee Court of Criminal Appeals finding that Roe's trial counsel did not provide constitutionally deficient representation cannot be said to be contrary to, or unreasonable applications of, *Strickland*. Questions of trial strategy are "virtually unchallengeable." See *Strickland*, 466 U.S. at 690. This court finds that Roe has no claim for relief based on trial counsel's advice not to subject himself to evaluation by the court appointed psychiatrist.

2. Allowing Roe's Jailer to Sit as a Juror

Roe's trial lawyers allowed one of his jailers to sit as a juror. Roe argues that the advice not to object to the juror constitutes ineffective assistance of trial counsel warranting a reversal of his conviction.

At the post-conviction relief hearing, Chandler testified that he "knew it was a little bizarre" to have one of Roe's jailers on the jury, but he stated that they had a "world

famous" jury consultant who advised keeping that juror. (Chandler Test., Hear. For Post-Conv. Rel. at 74:1-6.) Roe's lawyers felt that it would help his insanity defense to have a juror who had seen Roe when he was originally arrested and was incoherent and under suicide watch. (*Id.* at 74:6-11.) Roe objected to keeping the juror but Chandler decided it would be in Roe's best interests to empanel the jailer.

(*Id.* at 74:16-20.)

The Criminal Court of Shelby County denied Roe's petition for post-conviction relief on this issue and the Tennessee Court of Criminal Appeals affirmed, stating:

Again, decisions regarding jury challenges are tactical decisions not subject to being second-guessed by this Court. This claim of ineffective representation is also without merit.

Roe, 2002 WL 31624850, at *10.

The decisions of the Criminal Court of Shelby County and the Tennessee Court of Criminal Appeals finding that Roe's trial counsel did not provide constitutionally deficient representation cannot be said to be contrary to, or unreasonable applications of clearly established federal law.

The Sixth and Fourteenth Amendments guarantee criminal defendants the right to impartial jurors. *Moran v. Illinois*, 504 U.S. 719, 726-27 (1992). When a biased juror is impaneled, "prejudice under *Strickland* is presumed, and a new trial is required." *Hughes v. United States*, 258 F.3d 453, 457 (6th Cir. 2001).

To determine if a juror is biased, the court must answer the following questions: "did [the] juror swear that he could set aside any opinion he might hold and decide the case on the evidence, and should the juror's protestation of impartiality have been believed." *Patton v. Yount*, 467 U.S. 1025, 1036 (1984). "Qualified jurors need not, however, be totally ignorant of the facts and issues involved... It is sufficient if the juror can lay aside his impression or opinion and render a verdict based on the evidence presented in court." *Murphy v. Florida*, 421 U.S. 794, 800 (1975) (internal quotes and citations omitted).

If a juror is not biased, the normal *Strickland* test applies, and counsel "is granted deference when conducting voir dire. An attorney's actions during voir dire are considered to be matters of trial strategy. A strategic decision cannot be the basis for a claim of ineffective assistance unless counsel's decision is shown to be so ill-chosen that it permeates the entire trial with obvious unfairness... But the trial strategy itself must be objectively reasonable." *Miller v. Webb*, __F.3d __, 2004 WL 2101934, at *6 (6th Cir. 2004) (internal quotes and citations omitted).

Roe has presented no evidence that would lead the court to conclude that the juror in question was biased. The only evidence Roe has presented is 1) that the juror was Roe's jailer; and 2) the juror's post-conviction hearing testimony that "[differences] in Mr. Roe's demeanor from the jail and when he was in the courtroom" factored into his decision "somewhat." Neither of these pieces of evidence goes to the issues of: 1) whether the juror swore that he could set aside any opinions he might have held and decide the case on the evidence; and 2) whether that "protestation of impartiality" could be believed.

Because Roe has not demonstrated juror bias, the two pronged test applies to his counsel's decision to empanel his jailer as a juror. The Tennessee admittedly terse finding that this decision did not qualify as constitutionally deficient representation cannot be said to be contrary to, or an unreasonable application of, *Strickland*. Questions of trial strategy are almost unassailable. See *Strickland*, 466 U.S. at 690 (finding strategic choices of counsel to be "virtually unchallengeable"). This court finds that Roe has no claim for relief based on trial counsel's advice to empanel his jailer as a juror.

3. Not Analyzing Hair Sample to Develop Physical Evidence to Support Abuse of Ephedrine

Roe's trial lawyers did not have his hair analyzed for ephedrine content. Because the concentration of ephedrine found in an individual's hair is proportional to that individual's use of ephedrine, analysis of hair samples can give evidence of ephedrine abuse. (Lipman Test., Hear. For Post-Conv. Rel. at 51:1-20.) Roe argues that the decision not to analyze his hair for ephedrine constitutes ineffective assistance of trial counsel warranting a reversal of his conviction.

The Tennessee Court of Criminal Appeals denied Roe's petition for post-conviction relief on this issue stating:

such evidence would have required expert testimony for its introduction and explanation. Such expert testimony was precluded by the trial court's pretrial order and, given that we have concluded that the Defendant's trial lawyers were not ineffective in pursuing the strategy that resulted in that order, we further conclude that they were not ineffective in

failing to perform scientific tests that they knew they would not be able to introduce at trial.

Roe, 2002 WL 31624850, at *9.

The decision of the Tennessee Court of Criminal Appeals finding that Roe's trial counsel did not provide constitutionally deficient representation cannot be said to be contrary to, or an unreasonable application of, *Strickland*. For a claim of ineffective assistance of counsel to justify overturning a conviction the defendant must have been prejudiced. *Strickland*, 466 U.S. at 687. Roe cannot show prejudice because, as the state court found, even if his counsel had analyzed his hair samples, he would not have been able to present the evidence without expert testimony, which was barred. This court finds that Roe has no claim for relief based on trial counsel's failure to analyze his hair samples for ephedrine.

4. Not Calling James Hughes or Tracey Johnson as Witnesses

Roe's trial lawyers did not call James Hughes ("Hughes") or Tracey Johnson ("Johnson") as witnesses to testify to the "good health of the deceased the night before she was killed as well as the ephedrine abuse of the Defendant." (Pet. at 9.) Roe argues that the failure these witnesses constitutes ineffective counsel warranting a reversal of his conviction. to assistance of conviction.

Chandler testified at the post-conviction relief hearing that he did not call Hughes as a witness because he was not credible and he could have testified negatively about the relationship between Roe and his wife. (Chandler Test., Hear. for Post-Cony. Rel. at 74:23-75:5.) Chandler testified that he

did not call Johnson because he "did not like [Johnson's] body language. I didn't- I thought he was a- I didn't think-he painted Mr. Roe as a really nice guy." (*Id.* at 75:12-14.)

The Tennessee Court of Criminal Appeals Denied Roe's petition for post-conviction relief stating:

The Defendant's attorneys' decisions not to call these witnesses were made after reviewing their proposed testimony and after making a reasonable, informed judgment call that these witnesses would not be beneficial to the defense. This Court will not second-guess these strategic decisions. This issue is without merit.

Roe, 2002 WL 31624850, at *10.

The decision of the Tennessee Court of Criminal Appeals finding that Roe's trial counsel did not provide constitutionally deficient representation cannot be said to be contrary to, or unreasonable applications of, *Strickland*. As already noted, questions of trial strategy are "virtually unchallengeable." *Strickland*, 466 U.S. at 690. This court finds that Roe has no claim for relief based on trial counsel's decision not to call Hughes or Johnson as witnesses.

B. Prosecutorial Misconduct

1. State Commented in Closing Arguments on the Lack of Witnesses to Support the Diagnosis of Psychosis

The state commented in closing arguments on the lack of defense witnesses supporting the diagnosis of psychosis. (Pet. at 8.) Roe argues that this was prosecutorial misconduct warranting reversal of his conviction.

After determining that Roe did not bring this claim on direct appeal, the Tennessee Court of Criminal Appeals disposed of it on procedural grounds stating: "this issue could have been raised on direct appeal. Accordingly, this issue has been waived. *See* Tenn. Code Ann. § 40-30- [I] 06 (g).¹" *Roe*, 2002 WL 31624850, at *11.

The State argues that this issue was decided on a separate and independent state ground and should not be examined by this court. (Resp. Mot. for Judg. as a Mat. of Law at 10.) "When a state argues that a habeas claim is precluded by the petitioner's failure to observe a state procedural rule, the federal court must go through a complicated analysis." *Maupin v. Smith*, 785 F.2d. 135, 138 (6th Cir. 1986).

The first step in the analysis is for the court to "determine that there is a state procedural rule that is applicable to the petitioner's claim, and that the petitioner failed to comply with the rule." *Id.* at 138. Tenn. Code Ann. § 40-30-[1]06(g) states:

(g) A ground for [post-conviction] relief is waived if the petitioner personally or through an attorney failed to present it for determination in any proceeding before a court of competent jurisdiction in which the ground could have been presented...

Criminal defendants in Tennessee may raise claims of improper closing arguments by the State on direct appeal. *See, e.g., Terry v. State*, 46 S.W.3d 147 (Tenn. 2001) (considering on direct appeal a defendant's claim of

¹ At the time the state appellate court opinion was written the relevant code section was T.C.A. § 40-30-206(g).

prosecutorial misconduct during closing arguments). The Tennessee Court of Criminal Appeals opinion dealing with Roe's direct appeal states that Roe presented eight issues for review. None of the eight issues listed concerns the state's closing arguments. *State of Tennessee v. Roe*, No. 02C01-9702-CR-00054, 1998 WL 7107, at *1 (Tenn. Crim. App. Jan 12, 1998). Consequently, Tenn. Code Ann. § 40-30-106(g) is a procedural rule that applies to Roe's claim, with which Roe did not comply.

The second step in the analysis is for the court to "decide whether the state courts actually enforced the state procedural sanction." *Maupin*, 785 F.2d at 138. In this case the Tennessee Court of Criminal Appeals specifically refused to consider Roe's prosecutorial misconduct claim because of his default.

The third step in the analysis is for the court to "decide whether the state procedural forfeiture is an adequate and independent state ground on which the state can rely to foreclose review of a federal constitutional claim. This question generally will involve an examination of the legitimate state interests behind the procedural rule in light of the federal interest in considering federal claims." *Id.* at 138 (internal quotes and citations omitted). Roe has not advanced an argument that Tenn. Code Ann. § 40-30-106(g) is not an adequate and independent state ground.

The fourth step in the analysis is for the petitioner to demonstrate "cause and prejudice," *Id.* at 138. Roe has made no attempt to demonstrate cause or prejudice.

Roe's failure to follow state procedure when bringing this claim of prosecutorial misconduct bars this court from examining it.

2. State's Failure to Disclose Brady Evidence

The state failed to disclose to Roe that his deceased wife's parents had "signed a contract awarding them movie rights for the case." (Pet. at 8.) Roe claims that this information should have been disclosed under *Brady v. Maryland*, 373 U.S. 83 (1963), because it could have been used to impeach the testimony of his deceased wife's mother. Roe argues that this was prosecutorial misconduct warranting reversal of his conviction.

The Tennessee Court of Criminal Appeals denied Roe's petition for post-conviction relief on this issue stating:

We acknowledge, of course, that the prosecution is required to disclose to a criminal defendant evidence which is favorable and material to his or her guilt, including evidence which may be used to impeach the State's witnesses. *See generally*, [*Brady*, 373 U.S. at 87]; *Johnson v. State*, 38 S.W.3d 52, 55-56 (Tenn. 2001).

To establish a Brady violation, an aggrieved defendant must prove four things: (1) that he or she requested the information (unless the information is obviously exculpatory--in which case the State must disclose it whether requested or not); (2) that the State suppressed the information; (3) that the information was favorable to the defendant; and (4) that the information was material. *See Johnson*, 38 S.W.3d at 56.

Here, the Defendant testified that he became aware that Michelle's parents had signed a movie contract after reviewing a copy of the district attorney's file in

conjunction with filing his post-conviction petition. No copy of any document from the district attorney's file was introduced in support of this allegation. Even accepting this testimony at face value, however, the Defendant's claim of a Brady violation fails because the information does not meet the definition of "material."

Under Brady, withheld evidence is material "only if there is a reasonable probability that, had the evidence been disclosed to the defense, the result of the proceeding would have been different." *United States v. Bagley*, 473 U.S. 667, 682 (1985). Here, the "withheld" evidence could have been used to impeach Michelle's mother. However, Michelle's mother was not a key witness to the prosecution, and her bias was already established by her relationship to the victim. Furthermore, although Mr. Chandler testified that the information would have been "great cross examination," we fail to see how it would have helped the Defendant's case even if Michelle's mother's credibility had been completely destroyed at trial. Her testimony was simply not that important to the State's case. Accordingly, this issue is without merit.

Roe, 2002 WL 31624850, at *11.

The decision of the Tennessee Court of Criminal Appeals finding that the *Brady* violation was not material cannot be said to be contrary to, or an unreasonable application of, the Supreme Court's *Brady* doctrine. Whether the state appellate court correctly applied *Brady* and *Bagley* is unimportant. See *Schoenberger*, 290 F.3d at 834. The important question is whether the finding that the State's *Brady* violation was not material was "objectively unreasonable." *Id.* at 834. There is

nothing unreasonable about the state appellate court's determination that, because Roe's deceased wife's mother was a relatively unimportant witness, the failure to turn over evidence that could have been used to impeach her was not material. This court finds that Roe has no claim for relief based on the State's failure to disclose *Brady* evidence.

C. Due Process Denial-Juror was also *Roe's* Jailer

As noted above, one of Roe's jurors was also one of his jailers. (Pet. at 8.) Roe argues that this was a violation of his due process rights warranting reversal of his conviction.

The Tennessee Court of Criminal Appeals circumstances surrounding the juror as follows:

Larry Collins, one of the deputy jailers where the Defendant was housed pre-trial, testified at the post-conviction hearing that he had seen the Defendant in jail prior to serving as one of the Defendant's jurors. Mr. Collins stated that he worked on the floor where the Defendant was housed "a couple of times." He also stated that his having seen the Defendant in jail factored into his verdict "somewhat." However, Mr. Collins also testified that he listened to and looked at all the evidence and followed his oath as juror. Mr. Collins disclosed his status as one of the Defendant's jailers during voir dire.

Roe, 2002 WL 31624850, at *10.

The Tennessee Court of Criminal Appeals denied Roe's petition for post-conviction relief on this claim stating:

We disagree with the Defendant that Mr. Collins' service as one of his jurors violated his due process rights. Although Mr. Collins testified that his prior contact with the Defendant affected his verdict "somewhat,- the record does not reflect in what way his verdict was affected. Defense counsel hoped that Mr. Collins would prove a sympathetic juror because the Defendant had been on suicide watch for several days while in jail. Indeed, we may speculate that Mr. Collins was more reluctant to convict the Defendant than other jurors just as readily as we may speculate that he was more prone to convict the Defendant. However, this Court cannot find a constitutional violation based on speculation. It is the Defendant's burden to prove his allegations by clear and convincing evidence. The Defendant has not done so. Nor has he cited this Court to any rule of law holding that a jailer subsequently serving as a juror is, per se, a due process violation. Accordingly, we find this issue to be without merit.

Roe, 2002 WL 31624850, at 10.

The decision of the Tennessee Court of Criminal Appeals finding that empaneling Roe's jailer was not a violation of his due process rights cannot be said to be contrary to, or an unreasonable application of, established federal law. The presence of a biased juror violates the Sixth and Fourteenth Amendment rights of a criminal defendant. *Morgan*, 504 U.S. at 726-27. As already discussed, in this case there is no evidence of juror bias. *See supra* pp 15-16. This court finds that Roe has no claim for relief based on the fact that one of his jurors was also one of his jailers.

D. Actual Innocence

In his petition, Roe states:

There is evidence that the Defendant was actually innocent of the offense of first-degree murder Tennessee does not permit an avenue through post-conviction to show actual innocence, but proof introduced at an evidentiary hearing would show that the Defendant was incapable psychologically of forming the premeditation to commit murder in the first degree and was innocent of that offense.

(Pet. at 9.) The evidence Roe has submitted to support his claim of actual innocence consists of three documents: a statement by John M. Taylor, the Associate Commissioner for Regulatory Affairs for the Food and Drug Administration, that the FDA has banned Ephedra in part because it has harmful side effects, including inducement of psychosis; two medical papers discussing psychosis related to the use of Ephedra. (Sub. of New Evid. in Supp. Of Pet. To Vac. Tenn. Judg. Put. to 28 U.S.C. § 2254; Not. of Supp. New Sci. Evid. in Supp. of Mot. to Vac. Judg.; 2nd Sub. of Supp. Fact. Auth. in Supp. of Pet. to Vac. Tenn. Judg. Due to New Evid.)

Roe does not specify whether his claim of actual innocence is offered as a substantive constitutional claim, *see Herrera v. Collins*, 506 U.S. 390 (1992), or as a means of overcoming a procedural default, *see Schlup v. Delo*, 513 U.S. 298, 315 (1995) (noting that Schlup's claim of actual innocence "is thus not itself a constitutional claim, but instead a gateway through which a habeas petitioner must pass to have his otherwise barred constitutional claim considered on the merits").

Regardless of how Roe characterizes this claim, it is subject to summary dismissal. Roe's claim to actual innocence as a gateway to consideration of otherwise barred constitutional claims may only go forward if Roe has shown that "it is more likely than not that no reasonable juror would have convicted in the light of the new evidence."² *Id.* at 326-27. The new evidence that Roe has presented demonstrates that some people who take large amounts of Ephedrine coupled with other drugs become psychotic. Roe has not presented any new evidence about the level of his own use of Ephedrine, nor has he presented any new evidence that demonstrates that he in particular would become psychotic. Based on the new evidence Roe has presented it cannot be said that "it is more likely than not that no reasonable juror would have convicted [him]."

If Roe claims that he is in fact actually innocent, that claim also fails. In *Herrera v. Collins*, 506 U.S. 390 (1993), the United States Supreme Court stated:

We may assume, for the sake of argument in deciding this case, that in a capital case a truly persuasive demonstration of "actual innocence" made after trial would render the execution of a defendant unconstitutional, and warrant federal habeas relief if there were no state avenue open to process such a claim. But because of the very disruptive effect that entertaining claims of actual innocence would have on the need for finality in capital cases, and the enormous burden that having to retry cases based on often stale

² The only constitutional claim Roe has presented that the court has rejected due to procedural default is his claim of prosecutorial misconduct during the State's closing arguments.

evidence would place on the States, the threshold showing for such an assumed right would necessarily be extraordinarily high.

Id. at 417. Roe's claim of actual innocence fails because the new evidence he has asserted does not create "a truly persuasive demonstration of actual innocence." As already noted, the evidence Roe presents merely indicates that, in some instances, people who take high doses of ephedrine coupled with other drugs such as alcohol become psychotic. Roe has presented no evidence that he personally was psychotic at the time of the murder, such as new evidence of the amount of ephedrine and alcohol in his body. This court finds that Roe has no claim for relief based on actual innocence.

V. Appealability

The Court must also determine whether to issue a certificate of appealability. The statute provides:

- (1) Unless a circuit justice or judge issues a certificate of appealability, an appeal may not be taken to the court of appeals from:
 - A) the final order in a habeas corpus proceeding in which the detention complained of arises out of process issued by a State court; or
 - B) the final order in a proceeding under section 2255.
- (2) A certificate of appealability may issue under paragraph (1) only if the applicant has made a

substantial showing of the denial of a constitutional right.

- (3) The certificate of appealability under paragraph (1) shall indicate which specific issue or issues satisfy the showing required by paragraph (2).

28 U.S.C. § 2253(c); *see also* Fed. R. App. P. 22(b); *Lyons v. Ohio Adult Parole Auth.*, 105 F.3d 1063, 1073 (6th Cir. 1997) (district judges may issue certificates of appealability under the AEDPA). No § 2254 movant may appeal without this certificate.

In *Slack v. McDaniel*, 529 U.S. 473, 484-84 (2000), the Supreme Court stated that § 2253 is a codification of the standard announced in *Barefoot v. Estelle*, 463 U.S. 880, 893 (1983), which requires a showing that "reasonable jurists could debate whether (or for that matter, agree that) the petition should have been resolved in a different manner or that the issues presented were 'adequate to deserve encouragement to proceed further.'" *Slack*, 529 U.S. at 484 (quoting *Barefoot*, 463 U.S. at 893 & n.4).

The Supreme Court recently cautioned against undue limitations on the issuance of certificates of appealability:

[O]ur opinion in *Slack* held that a COA does not require a showing that the appeal will succeed. Accordingly, a court of appeals should not decline the application of a COA merely because it believes the applicant will not demonstrate entitlement to relief. The holding in *Slack* would mean very little if appellate review were denied because the prisoner did not convince a judge, or, for that matter, three judges, that he or she would prevail. It is consistent with §

2253 that a COA will issue in some instances where there is no certainty of ultimate relief. After all, when a COA is sought, the whole premise is that the prisoner "already failed in that endeavor."

Miller-El v. Cockrell, 537 U.S. 322, 337 (2003) (quoting *Barefoot*, 463 U.S. at 893). Thus,

A prisoner seeking a COA must prove "something more than the absence of frivolity" or the existence of mere "good faith" on his or her part ... We do not require petitioners to prove, before the issuance of a COA, that some jurists would grant the petition for habeas corpus. Indeed, a claim can be debatable even though every jurist of reason might agree, after the COA has been granted and the case has received full consideration, that petitioner will not prevail.

Id. at 1040 (quoting *Barefoot*, 463 U.S. at 893); *see also id.* at 1042 (cautioning courts against conflating their analysis of the merits with the decision of whether to issue a COA; "[t]he question is the debatability of the underlying constitutional claim, not the resolution of that debate.).³

In this case, there can be no question that any appeal by this petitioner on any of the issues raised in this petition does not deserve attention. The petitioner has failed to present any argument that the decision of the Tennessee Court of Criminal Appeals as to his state habeas petition was contrary to, or an

³ By the same token, the Supreme Court also emphasized that "[o]ur holding should not be misconstrued as directing that a COA always must issue." *Id.* at 1039. Instead, the COA requirement implements a system of differential treatment of Chose appeals deserving of attention from Chose that plainly do not." *Id.* at 1040.

unreasonable application of, clearly established federal law, or that it was based on an unreasonable determination of the facts in light of the evidence presented in the state court proceeding. The court therefore DENIES a certificate of appealability.

V. Conclusion

Petitioner has made out no claim for relief based on his allegations of ineffective assistance of trial counsel. Similarly, Petitioner's claims of prosecutorial misconduct, stemming from improper statements made in closing argument or the State's failure to disclose *Brady* evidence, furnish Petitioner with no claim for the petition, all of the outstanding motions addressed are DENIED as moot. Additionally, the court DENIES a certificate of appealability.

So ordered this 9th day of November 2004.

/s/ Samuel H. Mays, Jr.

UNITED STATES DISTRICT JUDGE

APPENDIX C

**IN THE UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

Case No. 03-2121-Ma/V

[September 28, 2004]

JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
JACK MORGAN, Warden,)
Respondent.)
)

ORDER REOPENING CASE

On March 29, 2004, the court entered an order staying this matter and on September 15, 2004, an order closing the case administratively was entered. Counsel for the petitioner filed a "Notice of Exhaustion of State Remedies" on September 22, 2004, and requested that this case be reopened. For good cause shown, this case is reopened and petitioner's petition pursuant to 28 U.S.C. §2254 will proceed.

It is so ORDERED this 28th day of September, 2004

36a

/s/ Samuel H. Mays, Jr.

UNITED STATES DISTRICT JUDGE

APPENDIX D

**IN THE UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

No. 03-2121 Ma/V

[March 29, 2004]

JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
JACK MORGAN, Warden,)
Respondent.)
)

ORDER STAYING CASE

This case involves Petitioner John Parker Roe's 28 U.S.C. § 2254 petition for writ of habeas corpus, filed on February 28, 2003. As described below, Roe continues to seek post-conviction relief from the Tennessee Supreme Court. The federal action is therefore STAYED until Roe has exhausted his state court remedies.

Roe was convicted of first-degree murder in the Criminal Court of Shelby County, Tennessee, on August 30, 1996. (Pet. at 1.) He appealed to the Tennessee Court of Criminal Appeals, which affirmed his conviction on January 12, 1998.

(*Id.* at 3.) Roe sought leave to appeal to the Tennessee Supreme Court, which denied his application for permission to appeal on January 4, 1999. (*Id.*) He filed a petition for certiorari in the Supreme Court of the United States, which was denied on June 7, 1999. (*Id.* at 4.) Roe then sought post-conviction relief in the Criminal Court of Shelby County. (*Id.*) That court conducted an evidentiary hearing and denied Roe's claim on October 31, 2000. (*Id.* at 5.) Roe appealed. The Tennessee Court of Criminal Appeals affirmed the trial court's denial of post-conviction relief, and the Tennessee Supreme Court denied Roe's application for permission to appeal on February 24, 2003. *See Roe v. State*, 2002 WL 31624850 (Tenn. Crim. App. Nov. 20, 2002), *denied*, Feb. 24, 2003. Roe filed the present 28 U.S.C. § 2254 petition for writ of habeas corpus on February 28, 2003, seeking to vacate his conviction. On October 1, 2003, Roe filed with this court a "Notice of Supplemental New Scientific Evidence in Support of Motion to Vacate Judgment," in which he presented evidence that he had not presented to the state courts. On December 31, 2003, Roe filed a "Second Submission of Supplemental Factual Authority in Support of Petition to Vacate Tennessee Judgment Due to New Evidence," and, on January 2, 2004, he submitted a "Notice of Filing/Submission of New Evidence" in support of his petition.

Respondent Jack Morgan filed a motion to strike Roe's supplemental filings and to dismiss Roe's petition without prejudice on January 12, 2004. In that motion, Morgan stated that *Roe* had filed a motion to reopen his post-conviction petition in the Criminal Court of Shelby County on October 8, 2003, and had provided to the state court the same evidence he had provided to this court in his October 1, 2003, "Notice of Supplemental New Scientific Evidence in Support of Motion to Vacate Judgment." (Mot. to Strike at 1 and

Attachment 1.) The trial court denied his motion to reopen, and Roe filed a notice of appeal on December 8, 2003. (*Id.* Attachments 2 and 3.) Morgan therefore moved the court to dismiss Roe's petition without prejudice because Roe is pursuing a state court motion to reopen his post-Conviction petition involving one of the issues he seeks to raise in his federal petition. (Mot. to Strike at 2.) Alternatively, Morgan requests that the court dismiss only Roe's unexhausted claims and stay further proceedings until Roe has exhausted those claims in state court. (*Id.* at 4.) Roe filed a response on January 14, 2004, in which he states that he "has no objection to this Court holding this petition in abeyance until the state court Motion to Re-Open has been fully exhausted." (Resp. at 1.)

Courts facing similar situations have stayed habeas actions pending the resolution of unexhausted claims in state court. In a concurring opinion in *Duncan v. Walker*, Justice Stevens stated that a district court could retain jurisdiction over a habeas claim and stay further proceedings pending the complete exhaustion of state remedies:

Indeed, there is every reason to do so when [the Antiterrorism and Effective Death Penalty Act] gives a district court the alternative of simply denying a petition containing unexhausted but nonmeritorious claims, see 28 U.S.C. §§ 2254(b) (2) (1994 ed., Supp. V), and when the failure to retain jurisdiction would foreclose federal review of a meritorious claim because of the lapse of AEDPA's 1-year limitations period.

533 U.S. 167, 182-183 (2001) (Stevens, J., concurring). See also *Godbolt v. Russell*, 82 Fed. Appx. 447, 451-52 (6th Cir. 2003) (approving the Second Circuit's approach of staying

federal habeas actions while allowing petitioner to present claims to the state court and instructing petitioner to return to federal court "normally 30 days" after exhaustion is completed).

Because Roe is currently pursuing state court relief on one claim he seeks to present in this court, and because dismissal of the petition could result in its being barred by the applicable statute of limitations, Roe's action is hereby STAYED pending resolution of his appeal of the state trial court's denial of his motion to reopen. If Roe wishes to move to lift the stay, he is instructed to do so within thirty days of having exhausted his state court remedies.

So ordered this 26th day of March 2004.

/s/ Samuel H. Mays, Jr.

UNITED STATES DISTRICT JUDGE

APPENDIX E

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE**

**PETITION UNDER 28 U.S.C. § 2254
FOR WRIT OF HABEAS CORPUS
BY A PERSON IN STATE CUSTODY**

<u>JOHN PARKER ROE</u>)
)
v.)
)
<u>DAVID MILLS, Warden</u>)
)

**Place of Confinement-Brushy Mountain Correctional
Complex, Site #2, P.O. Box 2000**

Prisoner No. #267074

PETITION

1. Name of location of court which entered the judgment of conviction under attack- Criminal Court for Shelby County, Tennessee at Memphis, Division V
2. Date of judgment of conviction- August 30, 1996
3. Length of sentence- Life

4. Nature of offense involved (all counts)- First Degree Murder
5. What was your plea? (Check one)
- (a) Not guilty ☒
 - (b) Guilty ☐
 - (c) Nolo contendere ☐

If you entered a guilty plea to one count or indictment, and a not guilty plea to another count or indictment, give details:

6. If you pleaded not guilty, what kind of trial did you have? (Check one)
- (a) Jury ☒
 - (b) Judge only ☐

7. Did you testify at trial?

Yes ☐ No ☒

8. Did you appeal from the judgment of conviction?
- Yes ☒ No ☐

9. If you did appeal, answer the following:

(a) Name of court- Tennessee Court of Criminal Appeals,
Western Division at Jackson, Tennessee

(b) Result-conviction affirmed

(c) Date of result and citation, if known- January 12,
1998

(d) Grounds raised

- a. Was the evidence sufficient as to premeditation and deliberation under the due process clause of the Fourteenth Amendment?
- b. Should the trial judge as "thirteenth juror" be weighing the evidence have set aside the guilty verdict of first degree murder as to the elements premeditation and deliberation or granted an acquittal for failure to prove sanity?
- c. Should the indictment have been dismissed on the grounds of double jeopardy under the Fifth Amendment to the United States Constitution as well as Article I, Section 10 of the Constitution of the State of Tennessee?
- d. Should the trial judge have denied the defense the testimony of expert witnesses at trial because the defendant refused to discuss the facts of the killing with the court-appointed expert?
- e. Should the state have been allowed to proceed with a death-qualified or "conviction prone" jury over defense objection on the grounds that there were no aggravating circumstances and in particular no "torture" when it appeared after the fact that the claim of torture was indeed wife abuse, insufficient as later ruled by the court to sustain the "aggravating circumstance"?
- f. Should the jail conversation with the Defendant have been suppressed on the grounds that it was illegally intercepted in violation of Title HI of the Omnibus Crime Control and Safe Streets Act as well as the Fourth Amendment to the United States

Constitution concerning the bag of videos or "sex toys"?

- g. Should the hearsay statements as to the deceased's state of mind to prove the Defendant's state of mind have been admitted over objection of the defense in violation of Tennessee Rule of Evidence 803 and the confrontation clause of the Sixth Amendment made applicable to the states by way of the Fourteenth Amendment due process clause?
- h. Should a mistrial have been declared on motion of Defendant on the grounds that the hearsay statement of Penny Mayes was Introduced illegally over objection and was highly prejudicial?
- (e) If you sought further review for the decision on appeal by a higher state court, please answer the following:
 - (1) Name of court- Tennessee Supreme Court
 - (2) Result- Application for Permission to Appeal denied
 - (3) Date of result and citation, if known January 4, 1999
 - (4) Grounds raised-
 - a. Whether the evidence is sufficient to support the jury's verdict that Roe was guilty of first degree murder.

- b. Whether the trial court properly overruled Roe's motion to dismiss the indictment on double jeopardy grounds.
- c. Whether the trial court properly disallowed any expert testimony pursuant to Rule 12.2(d) of the Rules of Criminal Procedure.
- d. Whether the jury selection process violated Roe's constitutional rights.
- e. Whether the trial about a conversation with Larry
- f. Whether the trial state of mind to Rule 803(3).
- g. Whether the trial court properly overruled Roe's motion for a motion for a mistrial.
- h. Whether the trial judge properly fulfilled his role as the thirteenth juror.
- (f) If you filed a petition for certiorari in the United States Supreme Court, please answer the following with respect to each direct appeal:
 - (1) Name of court- United States Supreme Court
 - (2) Result Petition for Writ denied
 - (3) Date of result and citation, if known
June 7, 1999
 - (4) Grounds raised- same as above

10. Other than a direct appeal from the judgment of conviction and sentence, have you previously filed any petitions, applications, or motions with respect to this judgment in any court, state or federal?

Yes [x] No[]

11. If your answer to 10 was "yes," give the following information:

(a) (1) Name of court- Criminal Court of Shelby County, Tennessee, Div V

(2) Nature of proceeding- Post-Conviction Relief

(3) Grounds raised

1. Mr. Roe's juror was also one of his jailers. This is an unconstitutional denial of the right to a fair and impartial jury under the due process clauses of the Tennessee and the United States Constitutions and the right to a fair trial under the Fourteenth Amendment of the United States Constitution and Article I, Section 9 of the Tennessee Constitution. Mr. Roe did not want this juror to sit on his case, and his attorneys were ineffective for advising him to do so. The court on its own motion should have excused the juror because obviously having seen Mr. Roe incarcerated tainted him. In addition, this juror based part of his decision on the change of demeanor for Mr. Roe between the times of his incarceration and his appearance in the courtroom.

2. Counsel was ineffective in this case for advising Mr. Roe not to submit to the court ordered examination by Dr. Lynne Zager. Counsel must have known that but not for that examination, they could not use any expert proof in order to present the only defense that Mr. Roe had, that of diminished capacity or insanity. Further, the court denied the Defendant the right to present an effective defense and the due process of law by first holding that they could present expert proof of diminished capacity and then later changing his mind in prohibiting him any other opportunity to be examined by the court ordered psychologist and thereby precluding him from presenting his defense of not having the culpable mental state to form the intent to commit murder in first or second degree.
3. Counsel was also ineffective for allowing a juror who was also his jailer to sit on the jury in this case thereby depriving him of a fair trial. Trial counsel was in also ineffective because CourtTV covering this case distracted them.
4. Trial counsel was also ineffective for not understanding the reciprocal discovery provisions of Rule 16. The State objected to the showing of documents to witnesses on cross-examination. The State contended that the introduction of said documents would be a violation of Rule 16 when, in fact, evidence used to impeach the State's witnesses is not covered by Rule 16.

5. Defense counsel never brought out during the guilt phase of the trial that one day prior to the shooting the victim told her mother that everything was fine.
6. Trial counsel was ineffective for not calling James Hughes as a witness who would have testified that he came over to the Roe house the night before the killing and Michelle answered the door and said that John was in the shower. She told him that they were going out to eat and to go to Wal-Mart to purchase some things for the house. He also asked her how they were doing and she said that they were fine. He would also say she had no bruises on her face and looked fine and normal to him. That would have impeached a prior witness who said that Michelle had bruises on the side of her face on or about that same day.
7. Counsel was also ineffective for not introducing the receipt from Wal-Mart which was in Defendant's wallet where they made the purchases that evening as well as a receipt from Golden Garden Oriental Restaurant where they ate supper the night before.
8. The court denied the Defendant the right to present an effective defense by first permitting him to present expert evidence of diminished capacity without submitting to this court ordered psychological examination and then changing its mind and prohibiting him from any further pursuit of said defense.

9. The jury improperly considered testimony they were told to disregard by the court in reaching their decision.
10. The Defendant was also denied due process of law by not having the opportunity to present expert testimony in the form of a neuropharmacologist, a psychiatrist and a clinical psychologist who would have testified about the combined effects of Ephedrine, alcohol and Sominex on his ability to form the requisite culpable mental state to form the intent to commit murder in the first or second degree.. Physical evidence corroborating this claim was not introduced.
11. Counsel was ineffective for failing to have crucial physical evidence tested and introduced at trial.
12. The State committed prosecutorial misconduct by objecting to the introduction of documents on cross-examination by defense counsel is a violation of Rule 16 when Rule 16 does not cover said documents.
13. The State committed prosecutorial misconduct by seeking the death penalty in this case when it knew under the law that its evidence could not support the aggravating circumstance that it alleged. That allowed the State to pick a more conviction prone jury who believed in the death penalty.

14. The State committed prosecutorial misconduct in its closing argument in rebuttal when Mr. Henderson argued on page 945 as follows:

"You all heard Mr. Emmons talk for however long it was. How many times did he say the words 'psychosis' or 'psychotic'? ...25/40 times? What witness--not lawyer--what witness testified to what psychosis even is, let alone that the defendant had one?--what witness? That's what's known as lawyer talk and it's a common device, and I will even admit some of the assistants use it, but here's the way that goes."

Mr. Henderson well knew that there were witnesses prepared to testify who were experts that Mr. Roe was suffering from a mental disease or defect at the time of the killing and were so prepared to testify to argue that there were no witnesses when he knew better is certainly prosecutorial misconduct.

15. The State committed prosecutorial misconduct by failing to inform the Defendant under *Brady* that the parents of the deceased had signed a contract awarding movie rights concerning this case and were paid a fee with future benefits as well. The information could have been used on cross-examination of the mother of the deceased to show bias.

51a

(4) Did you receive an evidentiary hearing on your petition, application or motion?

Yes [x] No []

(5) Result- Petition denied

(6) Date of result- October 31, 2000

(b) As to any second petition, application or motion give the same information:

(1) Name of court

(2) Nature of proceeding

(3) Grounds raised

(4) Did you receive an evidentiary hearing on your petition, application or motion?

Yes [] No []

(5) Result

(6) Date of result

(c) Did you appeal to the highest state court having jurisdiction the result of action taken on any petition, application or motion?

(1) First petition, etc. Yes [x] No []

(2) Second petition, etc. Yes [] No []

(d) If you did not appeal from the adverse action on any petition, application or motion, explain briefly why you did not:

12. State *concisely* every ground on which you claim that you are being held unlawfully. Summarize *briefly the facts* supporting each ground. If necessary, you may attach pages stating additional grounds *and facts* supporting same.

CAUTION: In order to proceed in the federal court, you must ordinarily first exhaust your available state court remedies as to each ground on which you request action by the federal court. If you failed to set forth all grounds in this petition, you may be barred from presenting additional grounds at a later date.

For your information, the following is a list of most frequently raised grounds for relief in habeas corpus proceedings. Each statement preceded by a letter constitutes a separate ground for possible relief. You may raise any grounds which you may have other than those listed if you have exhausted your state court remedies with respect to them. However, you *should d raise in this petition all available grounds* (relating to this conviction) on which you base your allegations that you are being held in custody unlawfully.

Do not check any of these listed grounds. If you select one or more of these grounds for relief, you must allege facts. The petition will be returned to you if you merely check (a) through G) or any one of these grounds.

- (a) Conviction obtained by plea of guilty which was unlawfully induced or not made voluntarily with

understanding of the nature of the charge and the consequences of the plea.

- (b) Conviction obtained by use of coerced confession.
- (c) Conviction obtained by use of evidence gained pursuant to an unconstitutional search and seizure.
- (d) Conviction obtained by use of evidence obtained pursuant to an unlawful arrest.
- (e) Conviction obtained by a violation of the privilege against self-incrimination.
- (f) Conviction obtained by the unconstitutional failure of the prosecution to disclose to the defendant evidence favorable to the defendant.
- (g) Conviction obtained by a violation of the protection against double jeopardy.
- (i) Denial of effective assistance of counsel.
- (j) Denial of right of appeal.

A. Ground one: Was trial counsel ineffective and was the Defendant denied due process of law by trial counsel advising him not to submit to the psychological examination by the court appointed psychologist?

Supporting FACTS (state *briefly* without citing cases or law)

Trial counsel advised the Defendant not to submit to the court ordered psychological examination by the State's

psychologist even though trial counsel knew that he would not be able to raise the defense of diminished capacity, a mental defense, as a result. That was his only defense.

B. Ground two: Was the Defendant denied due process of law by virtue of the fact that one of his jurors was also one of his jailers? Was trial counsel ineffective for not objecting to the juror sitting?

Supporting FACTS (state *briefly* without citing cases or law)

One of the jurors sitting on Mr. Roe's case was one of his jailers. The jailer testified at the post-conviction hearing that it certainly affected him to see Mr. Roe in custody in jail. Trial counsel did not object to that juror sitting in judgment at trial.

C. Ground three: Was trial counsel ineffective for not developing physical evidence to support the abuse of ephedrine with a hair sample? Did the State commit prosecutorial misconduct by commenting in closing argument that there were no witnesses to support the diagnosis of psychosis when the State Knew through its own when he well knew that testimony which had been excluded would support that diagnosis?

Supporting FACTS (state *briefly* without citing cases or law)

There was available to the defense at trial a hair sample which could have been tested to support the abuse of Ephedrine by the Defendant. The same hair sample was tested and presented through the testimony of Dr. Jonathan Lipman, a neuropharmacologist, at the post-conviction hearing

indicating that the levels of Ephedrine were the highest he has ever seen where certainly at the extremely abusive levels.

The prosecutor at the closing argument argued that there were no witnesses to support the diagnosis of psychosis of the Defendant. He knew very well there were such witnesses and that none could be presented because of the ineffective assistance of counsel in not permitted the Defendant to be examined by the State psychologist.

D. Ground four Did the State commit prosecutorial misconduct by failing to inform the Defendant under *Brady* that the parents of the deceased had signed a contract awarding them movie rights for the case?

Supporting FACTS (state *briefly* without citing cases or law)

Prosecution knew and did not tell the defense that the parents' of the deceased had signed a movie contract. Said contract could be used to show bias and could have been used impeach the mother of the deceased who testified at trial.

E. Ground five Was trial counsel ineffective for failing to call witnesses James Hughes, Tracey Gossett and not producing receipts from Wal-Mart as well as from Golden Garden Oriental where the Petitioner and his wife shopped and ate the evening before she was killed?

Supporting FACTS (state *briefly* without citing cases or law)

James Hughes and Tracy Gossett were available to testify at trial as to the good health of the deceased the night before she was killed as well as the Ephedrine abuse of the

Defendant. The receipts could have been introduced to show that on the night immediately before the morning when the deceased was killed, the Defendant and the deceased went to Wal-Mart and went out to dinner at the Golden Garden Oriental Restaurant.

F. Ground Six There is evidence that the Defendant was actually innocent of the offense of first-degree murder.

Supporting FACTS (state *briefly* without citing cases or law)

Tennessee does not permit an avenue through post-conviction to show actual innocence, but proof introduced at an evidentiary hearing would show that the Defendant was incapable psychologically of forming the premeditation to commit murder in the first degree and was innocent of that offense

13. If any of the grounds listed in 12 A, B, C, D, E and F were not previously presented in any other court, state or federal, state *briefly*, what grounds were not so presented, and give your reasons for not presenting them:

The only ground not previously raised in state court is that of actual innocence.

14. Do you have any petition or appeal how pending in any court, either state or federal, as to the judgment under attack?

Yes[] No [x]

15. Give the name and address, if known, of each attorney who represented you in the following stages of the judgment attacked herein:
- (a) At preliminary hearing- Hansom, 659 Freeman, Memphis, TN 38122
 - (b) At arraignment and plea- Wayne Emmons, 242 Poplar Avenue, Memphis, TN
 - (c) At trial- Wayne Emmons and Ed Chandler, 8532 Old Brownsville, Arlington, TN 38002
 - (d) At sentencing Wayne Emmons and Ed Chandler
 - (e) On appeal Wayne Emmons and Ed Chandler
 - (f) In any post-conviction proceeding Douglas A. Trant, 900 S. Gay Street, Suite 1502, Knoxville, TN 37902
 - (g) On appeal from any adverse ruling in a post-conviction proceeding Douglas A. Trant
16. Were you sentenced on more than one count of an indictment, or on more than one indictment, in the same court and at the same time?
- Yes[] No [x]
17. Do you have any future sentence to serve after you complete the sentence imposed by the judgment under attack?
- Yes [] No [x]

58a

- (a) If so, give name and location of court which imposed sentence to be served in the future:
- (b) Give date and length of above sentence:
- (c) Have you filed, or do you contemplate filing, any petition attacking the judgment which imposed the sentence to be served in the future?

Yes []

No [x]

Wherefore, petitioner prays that the Court grant petitioner relief to which he may be entitled in this proceeding.

/s/ Doug Trant

Signature of Attorney

DOUGLAS A. TRANT

900 S. Gay Street

Suite 1502

Knoxville, TN 37902

APPENDIX F

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE
AT MEMPHIS**

No. 03CV212MaV

JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
DAVID MILLS, Warden,)
Respondent.)
)

**SUBMISSION OF NEW EVIDENCE IN SUPPORT OF
PETITION TO VACATE TENNESSEE JUDGMENT
PURSUANT TO 28 U.S.C. § 2254**

Comes the Petitioner, John Parker Roe, by and through counsel, Douglas A. Trant, to submit as new evidence the attached documents from the United States Federal Drug Administration indicating that the USFDA is banning the sale of Ephedrine products including Ephedra in the United States. The USFDA has made this decision because of the inherent dangers in taking any Ephedrine products. As the attached paper from John M. Taylor, Associate Commissioner for Regulatory Affairs for the Food and Drug Administration, on page 6, in the second to last full paragraph indicates, adverse effects associated with Ephedrine include psychosis.

This new evidence is a government corroborates of the position that the Petitioner has taken in submitting new evidence concerning Ephedrine. This evidence corroborates other evidence submitted by Petitioner indicating that he was not mentally capable of forming the intent to commit premeditated murder. The evidence shows, therefore, that he is innocent of the offense of murder in the first degree.

Respectfully submitted,

/s/ Douglas A. Trant, #6871

900 S. Gay Street

Suite 1502

Knoxville, TN 37902

(865) 525-7980

Signed in other than black ink for security purposes

CERTIFICATE OF SERVICE

I hereby certify that I have mailed or delivered a true and exact copy of the foregoing document to Elizabeth B. Marney, Assistant Attorney General, P.O. Box 20207, Nashville, TN 37202, on this the 30th day of December, 2003.

/s/ Douglas A. Trant

U.S Food and Drug Administration

Consumer Alert

P03-106

FOR IMMEDIATE RELEASE

December 30, 2003

Media Inquiries: 301-827-6242

Consumer Inquiries: 888-1NFO-FDA

Consumer Alert:

**FDA Plans Regulation Prohibiting Sale of Ephedra-
Containing Dietary Supplements and Advises Consumers to
Stop Using These Products**

The Food and Drug administration (FDA) is alerting the public to its forthcoming determination that dietary supplements containing ephedra present an unreasonable risk of illness or injury, and should not be consumed. The agency has notified firms manufectudn9 and marketing these products that it intends to issue a final rule prohibiting their sale, which will become effective 60 days alter its publication.

The FDA has taken this step alter conducting an exhaustive and highly resource-intensive process required under the Dietary Supplement Health and Education Act (DSHEA) of 1994 for banning a dietary supplement that presents a significant and unreasonable risk to human health.

To meet this challenging standard, the FDA gathered and thoroughly reviewed a prodigious amount of evidence about ephedra's pharmacology; clinical studies of ephedra's safety and effectiveness; newly available adverse events reports; the published literature; and a seminal report by the RAND

Corporation, an independent scientific institute. The FDA also reviewed tens of thousands of public comments on the agency's request in February, 2003 for information about ephedra-associated health risks.

The totality of the available data showed little evidence of ephedra's effectiveness except for short-term weight loss, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system. These reactions have been conclusively linked to significant adverse health outcomes, including heart ailments and strokes.

By informing more than 60 dietary supplement firms about the upcoming final rule, FDA is sending a strong and unambiguous signal that dietary supplements containing ephedrine alkaloids present an unreasonable risk. Consumers are urged to stop buying and using these products immediately.

Ephedra, also celled Ma Huang, is a naturally occurring substance derived from botanicals. Its principal active ingredient is ephedrine, which when chemically synthesized is regulated under the Federal Food, Drug and Cosmetic Act of 1938 as a drug. In contrast to the DSHEA-regulated dietary supplements that contain natural ephedra, the safety and effectiveness of the synthesized ephedrine has to be proven by the manufacturer, not the FDA. In recent years ephedra products have been extensively promoted for aiding weight control and boosting sports performance and energy.

Today's announcement is a continuation of a process that started in June, 1997 when FDA first proposed to require a statement on dietary supplements with ephedra warning that they are hazardous and should not be used for more than 7 days. FDA modified this proposed rule in 2000, and in

February 2003 it announced a series of measures that included strong enforcement actions against firms making unsubstantiated claims for their ephedra-containing products.

These measures have prompted voluntary compliance with FDA rules, voluntary product recalls, FDA warning letters, seizures and injunctions, criminal actions, and joint enforcement actions with the Federal Trade Commission and the Department of Justice. (More detail on these actions can be found at <http://www.fda.gov/ola/2003/dietarysupplements.1028.html>) As a result, ephedra-containing dietary supplements advertised for enhanced sport performance have been removed from the market, there has been a significant decline in the demand for ephedra products, and many firms have stopped their marketing.

Additional information relating to today's announcement is available online at www.cfsan.fda.gov/~dms/ds-ephed.html

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STATEMENT OF JOHN M. TAYLOR
ASSOCIATE COMMISSIONER FOR REGULATORY
AFFAIRS FOOD AND DRUG ADMINISTRATION
BEFORE THE COMMITTEE ON COMMERCE
UNITED STATES SENATE

OCTOBER 28, 2003

INTRODUCTION

Thank you Mr. Chairman, for this opportunity to testify at this hearing on dietary supplements and the current regulations to protect American consumers from the potential adverse health risks associated with the use of certain supplements. I am John M. Taylor, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration (FDA or the Agency). In my statement today, I will address FDA actions to implement DSHEA, especially our regulations development adverse event monitoring, and enforcement posture. I will also address FDA actions on two major types of dietary Supplements that are of current concern, ephedra and steroid precursors. But first, let me provide you a short background on dietary supplements.

BACKGROUND ON REGULATION OF DIETARY SUPPLEMENTS

Nearly half of the population of the United States uses "dietary supplements" The Dietary Supplement Health and Education Act of 1994 (DSHEA) establish a unique regulatory framework in an attempt to strike the right balance between providing consumer access to dietary supplements that they chose to use to help maintain and improve their health, and

giving the FDA the necessary regulatory authority to take action against supplements or supplement ingredients that present safety problems, make false or misleading claims, or are otherwise adulterated or mishandled. Although dietary supplements are generally regulated as foods, there are special statutory provisions and implementing regulations for dietary supplements that differ in some respects from those covering conventional foods. Moreover, the regulatory requirements for dietary supplements also differ from those that apply to prescription and over-the-counter (OTC) drug products.

Congress defined the term dietary supplement as a product that, among other things, is ingested, is intended to supplement the diet, is labeled as a dietary supplement, is not represented as a conventional food or as a sole item of a meal or the diet, and that contains at least one dietary ingredient. The dietary ingredients in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and dietary substances such as enzymes. Dietary ingredients also can be metabolites, constituents, extracts, concentrates, or combinations of the preceding types of ingredients. Dietary supplements may be found in many forms, such as tablets, capsules, liquids, or bars. DSHEA placed dietary supplements in a special sub-category under the general umbrella of foods, but products that meet the drug definition are subject to regulation as drugs.

LABELING OF DIETARY SUPPLEMENTS

Under the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA's implementing regulations, the label of a dietary supplement must include:

APPENDIX G

**UNITED STATES DISTRICT COURT WESTERN
DISTRICT OF TENNESSEE AT MEMPHIS**

No. 03CV2121MaV

_____ JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
STATE OF TENNESSEE,)
Respondent.)
_____)

**SUBMISSION OF AFFIDAVIT IN SUPPORT OF
PETITION PURSUANT TO 28 U.S.C. § 2254**

Comes the Petitioner, John Parker Roe, by and through counsel, Douglas A. Trant, to submit the attached affidavit in support of his motion to vacate judgment pursuant to 28 U.S.C. § 2254.

Respectfully submitted,

/s/ Douglas A. Trant, #6871
900 S. Gay Street, Suite 1502
Knoxville, TN 37902
(865) 525-7980

Signed in other than black ink for security purposes

AFFIDAVIT OF JOHN PARKER ROE

I, John Parker Roe, have reviewed the Petition filed on my behalf pursuant to 28 U.S.C. § 2254 and find that it is true and correct.

/s/ John Parker Roe

STATE OF TENNESSEE)
)
COUNTY OF MORGAN)

Sworn to and subscribed before me this 4th day of March, 2003.

/s/ _____
Notary

My Commission Expires: 9/29/04

APPENDIX H

**UNITED STATES DISTRICT COURT WESTERN
DISTRICT OF TENNESSEE AT MEMPHIS**

No. 03CV2121MaV

<u>JOHN PARKER ROE,</u>)
Petitioner,)
)
v.)
)
STATE OF TENNESSEE,)
Respondent.)
<u></u>)

**NOTICE OF SUPPLEMENTAL NEW SCIENTIFIC
EVIDENCE IN SUPPORT OF MOTION
TO VACATE JUDGMENT**

Comes the Petitioner, John Parker Roe, by and through counsel, Douglas A. Trant, to submit the additional scientific evidence attached to this admission in support of his position that new scientific evidence available supports his actual innocence in this cause.

Respectfully submitted,

/s/ Douglas A. Trant, #6871
900 S. Gay Street
Suite 1502
Knoxville, TN 37902
(865) 525-7980

Signed in other than black ink for security purposes

CERTIFICATE OF SERVICE

I hereby certify that I have mailed or delivered a true and exact copy of the foregoing document to Paul G Summers, State Attorney General, P.O. Box 20207, Nashville, TN 37202, on this the 26th day of September, 2003.

/s/ Douglas A. Trant

Psychosis Related to Ephedra, Containing Herbal Supplement Use

Ruth Walton, MD, Gall H. Manos, MD

South Med J 96(7):718-720, 2003. © 2003 Lippincott
Williams & Wilkins

Abstract and Introduction

Abstract

Ephedra, a psychoactive substance with stimulant properties, is found in many herbal products. Often perceived by the lay public as benign, the potential health-related dangers of using these products are beginning to be recognized. We review four cases associated with ephedra-containing herbal products and report three additional cases. Unlike the previously reported cases, the patients presented in this report developed persistent psychosis that required psychopharmacologic management.

Introduction

Ephedrine, a naturally occurring substance found in various species of the *Ephedra* genus (also known as *ma Huang*), has been used in China for more than 2,000 years, it was introduced into Western medicine approximately 70 years ago as the first orally active sympathomimetic. Ephedrine is completely absorbed with oral administration, is distributed throughout the body, and crosses the blood-brain barrier. Ephedrine and other sympathomimetic drugs (eg, cocaine, methamphetamine) are derived from phenylethylamine. They differ only by a single substitution on the benzene ring, the terminal amino group, the α carbon, or the β carbon.¹

Although a urine drug screen that is positive for the presence of stimulants may suggest that ephedrine-induced psychosis is present, the symptoms may be indistinguishable from those of a primary psychosis disorder, and the presence of ephedrine may not account for the psychosis. Although cocaine and amphetamines are readily recognized as stimulants and are specifically tested for in urine drug screens, herbal substances that contain ephedrine may be overlooked. Ephedrine is not specifically tested for in urine drug screens but may result in a false-positive result for amphetamines on qualitative tests. More specific quantitative tests can differentiate between amphetamines and ephedrine. Three cases of substance-induced psychosis in connection with the use of herbal dietary supplements are reported.

Case Reports

Patient 1

A 19-year-old man was referred for psychiatric evaluation because of decreased sleep, increasingly aggressive and disorganized behavior and paranoid delusions during a 1-week period, it was reported that he recently had been using over-the-counter ephedra-containing herbal weight-training supplements (eg Ripped Fuel, Twin Laboratories, Inc., Hauppauge, NY; Hydroxycut, MuscleTech Research and Development, Inc., Mississauga, ON, Canada) and had been escalating the doses and even inhaling the supplements through his nose in powder form. The patient's psychiatric history and substance use history were unremarkable. The family psychiatric history was negative.

His physical examination was unremarkable with the exception of an elevated lactic dehydrogenase level of 769 IU/L and an alanine transferase level of 142 IU/L, both of

which returned to normal after 2 weeks of observation. His urine drug screen was initially positive for amphetamine, but confirmation studies (a more specific quantitative assay with the same sample) were negative for amphetamine.

He was observed in the hospital for 2 days without medications. He became increasingly hostile, assaultive, and disorganized. He was administered valproate, clonazepam, and haloperidol for persistent manic and psychotic symptoms. Gradually, his symptoms abated, and he was released for outpatient follow-up. The antipsychotic and benzodiazepine medications were discontinued after approximately 80 days without further psychotic symptoms. At the time of his last follow-up 5 months later, the patient remained on valproate only and was symptom-free.

Patient 2

A 21-year-old man who had experienced a brief psychotic episode after Hydroxycut use approximately 1 year earlier presented with recurrent manic and psychotic symptoms manifested by decreased sleep and increasing agitation with grandiose, prosecutory, and referential delusions. During the year between psychotic episodes, the patient had used Hydroxycut in increasing doses for brief periods without psychotic symptoms until the most recent episode, which followed a 2-week Hydroxycut binge. There was no other substance abuse history. The family psychiatric history was unremarkable. The patient's physical examination and laboratory studies were unremarkable except for the presence of global cerebral atrophy seen on a computed tomographic scan.

Because his first episode of psychosis had resolved quickly after discontinuation of the Hydroxycut, the patient initially

was observed in the hospital for 5 days without medications. His psychotic symptoms did not abate, however, and he was administered olanzapine. He was discharged on the 10th hospital day with continued outpatient follow-up. He remained asymptomatic on medications until his medical discharge from the military 2 months later.

Patient 3

A 33-year-old man presented with a 2-week history of depressive symptoms, suicidal ideation, auditory hallucinations, and paranoid and grandiose delusions. These symptoms coincided with his use of the diet aid Metabolife, which contains ma Huang. He denied other substance use and denied prior herbal supplement use. His psychiatric history and family psychiatric history were unremarkable. His physical examination and laboratory studies were unremarkable.

The patient was hospitalized, observed without medication use, and discharged after 5 days with apparent resolution of his symptoms. Ten days later, the patient presented in the emergency department complaining of recurrence of his previously described psychotic symptoms. He denied resumption of herbal product or other substance use. Treatment with antipsychotic medication was then initiated and titrated to effect with remission of symptoms during the next 3 weeks. Three months later, the patient remained asymptomatic and his medication was tapered during a 4-week period. He did well for an additional 4 months but was restarted on quetiapine after he experienced recurrence of paranoid ideation.

Discussion

There are numerous ma Huang-containing herbal dietary supplements available on the market that are advertised for various uses, including bodybuilding, weight loss, enhanced energy, or improved memory (eg, Ripped Fuel, Hydroxycut; Metabolife, Metabolife International, Inc., San Diego, CA; Herbalife, Herbalife, Inc., Century City, CA; Energel, PVL NuVients, Ltd., Port Coquitlam, BC, Canada; herbal ecstasy, herbal phen-fen). Ma Huang, which is derived from plants of the genus *Ephedra*, contains the alkaloids nomphehrine, norpseudosphedrine, pseudoephedrine, and ephedrine, with the first two being minor components and ephedrine accounting for 30 to 90% of the total alkaloid content. Pseudosphedrine, which is the second major constituent in most ma Huang-containing products, is less potent and less likely to cause central nervous system stimulation.² The actual amount of ephedrine and other ephedra alkaloids found in a product depends on which *Ephedra* species is used (more than one species may be used in a given product), where the plant is grown, the type of growing conditions, and the time of the harvest. These facts determine not only the differences in ephedrine content between products but also within batches of the same product. High-performance liquid chromatographic assessment of ma Huang-containing herbal products have demonstrated 5- to 20- fold variance in ephedrine and pseudoephedrine content in products with the same amount of ma Huang extract reported on the label and even within different lots of the same product.³

Ephedrine psychosis has been reported in multiple cases since its introduction into Western medicine as a bronchodilator in 1930. Whitehouse and Duncan⁴ reviewed 20 such cases and found that there was no personal or family history of psychosis in 18 of the cases, that 80% of the

patients had taken ephedrine for more than 1 year, that a majority of patients had gradually increased the dose, and that the average dose before the psychotic episode was 510 mg. The typical clinical picture for these patients was that of paranoid psychosis, with roughly one-third having affective symptoms. Cases of psychosis resulting from the use of synthetic nophedrine and pseudosphedrine have also been described. Lambert⁵ reported an example of this presentation in a case of paranoid psychosis in a 55-year-old man after abuse of Contact 400 (GlaxoSmithKline, Research Triangle Park, NC), which contained phenylpropanolamine (nophedrine). He also described the case of a 32-year-old policeman who developed visual hallucinations, auditory hallucinations, and paranoid delusions after abuse of Actifed (Pfizer, Inc., New York, NY), which contained pseudoephedrine.

The potential health risks arising from herbal substances containing botanical ephedrine have been recognized. Toxicity may occur at only two or three times the maximum therapeutic dose of 150 mg/d.⁶ Most reports have focused on medical complications such as stroke, seizure, hepatic toxicity, or even death.⁷⁻⁹ A search of English-language publications revealed only four previously reported cases of psychosis developing subsequent to use of ma huang-containing herbal products. Capwell¹⁰ reported the case of a 45-year-old man with a 2-month history of daily herbal diet supplement use who developed behavior and personality changes. After discontinuing use of the herbal supplement, the patient's symptoms resolved by the third day and remained symptom-free for more than 1 year. Doyle and Kargin¹¹ described the case of a 34-year-old man who jumped out an upstairs window to escape imagined attackers after using ma Huang for 10 days. This patient's symptoms also rapidly resolved during a 2-week hospitalization. Katz¹² described

the case of a 39 year-old man who developed manic and psychotic symptoms after bingeing for 72 hours on excessive amounts of Herbalife in both pill and concentrated powder form. This man's symptoms resolved rapidly within 24 hours after hospital admission. Jacobs and Hirsch presented the case of a 20-year-old man who became paranoid and psychotic after several months of using ma Huang, ginseng, dehydroepiandrosterone, creatine, and coffee. Although initially treated with antipsychotic medication, the medication was discontinued as the patient's symptoms abated.

Conclusion

Psychosis associated with ma Huang-containing herbal product use seems to be relatively rare, and in three of the four previously reported cases, symptoms resolved rapidly without administration of antipsychotic medication after the substance use was discontinued. Our cases differed in that the psychotic symptoms did not remit quickly and antipsychotic medications were required to control the patients' symptoms. Although we think that the use of ephedra-containing herbal preparations accounted for the psychiatric symptoms observed, or that at least they were a contributing factor, it is possible that herbal use was only a fortuitous finding coincident to the onset of a primary psychotic disorder. Although psychosis as a result of the use of over-the-counter medications containing psychoactive substances has long been recognized, the clinician must recognize the risk that exists with the use of herbal products that contain ephedra alkaloids.

Presented at the Society of Uniformed Service Psychiatrists Annual Meeting, APA, May 5, 2001, New Orleans, 1.4.

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Sidebar: Key Points

- * Ephedrine is a naturally occurring substance found in certain species of the ephedra plant, also known as ma Huang.

Disclaimer

The patients described in this article were admitted to the inpatient unit of the Department of Psychiatry, Naval Medical Center Portsmouth, Portsmouth, VA 23708.

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APPENDIX I

**UNITED STATES DISTRICT COURT WESTERN
DISTRICT OF TENNESSEE AT MEMPHIS**

No. 03CV2121MaV (MAYS/VESCOVO)

JOHN PARKER ROE,)
Petitioner,)
)
v.)
)
DAVID MILLS, Warden,)
Respondent.)

**SECOND SUBMISSION OF SUPPLEMENTAL
FACTUAL AUTHORITY IN SUPPORT OF PETITION
TO VACATE TENNESSEE JUDGMENT DUE TO
NEW EVIDENCE**

Comes the Petitioner, John Parker Roe, by and through counsel, Douglas A. Trant, to submit the attached additional and new evidence of the ephedrine psychosis which would prove the innocence of the Petitioner of the conviction of murder in the first degree.

81a

Respectfully submitted,

/s/ Douglas A. Trant, #6871

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Knoxville, TN. 37902

(865) 525-7980

Signed in other than black ink for security purposes

CERTIFICATE OF SERVICE

I hereby certify that I have mailed or delivered a true and exact copy of the foregoing document to Elizabeth B. Mamey, Assistant Attorney General, P.O. Box 20207,

Nashville, TN 37202, on this the 22 day of December, 2003.

/s/ Douglas A. Trant

**Acute Psychosis due to the Interaction of Legal
Compounds - Ephedra Alkaloids in 'Vigueur Fit'
Tablets, Caffeine in 'Red Bull' and Alcohol**

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ABSTRACT

A short-lasting episode of acute psychosis in a 32-year-old male which followed the consumption of alcohol, caffeine and 'vigueur fit' tablets containing ephedra alkaloids is reported. Less than two days after the event, a urine sample contained 22 ug/ml of ephedrine and 5 pg/ml of pseudoephedrine. Despite detailed pharmacological evidence being given at a jury trial, he was convicted of assault and trespass and was fined £16,000. An earlier, incident involving misbehavior on an aircraft again involving alcohol and ephedrine resulted in a conviction and a court order to provide twice weekly urine tests for alcohol for a period of six months. He stopped taking the alkaloid tablets after the second incident. There was no history of aberrant behaviour in this man outwith the period when taking these tablets. Ephedra alkaloids may cause psychosis and their effects can be exaggerated by interaction with caffeine and ethanol. To protect the public, the use of stimulant drugs in over-the-counter weight control,

programmes should be prescription only and the package insert should include a warning on the dangers of concomitant use of ethanol.

INTRODUCTION

Ephedrine-containing remedies are frequently used for coughs and colds and as an adjunct to weight reduction. Interactions of these legal drugs or 'dietary supplements' with caffeine and alcohol may have untoward consequences. Data on adverse cardiovascular and central nervous system effects of ephedra alkaloids reported to the FDA between 1997 and 1999 have been reviewed. Hypertension, tachy-cardia, palpitations, stroke, seizures, disability and death were recorded. The authors concluded that dietary supplements containing ephedra alkaloids posed a serious health risk to some users (Hailer and Benowitz, 2000). Despite the risks, clinical trials on the treatment of obesity still use anorexic compounds containing a combination of ephedrine and caffeine with daily doses of 60 mg ephedrine and 600 mg caffeine with few problems (Toubro and Astrup, 1997).

CASE REPORT

In May 1998, a 32-year-old male who had been obese for about five years, weighed 114 kg (BMI 36) despite medical advice and dieting. Acquaintances advised him of the efficacy of 'vigueur fit' tablets available from a health food store. He took six to nine tablets daily without fail. This is about twice the recommended dose. His appetite was reduced. He felt energized and started to take ten mile walks early in the morning. This resulted in about 26 kg weight loss in about nine months.

In December 1998, he misbehaved on a transatlantic flight after heavy alcohol consumption, throwing blankets and causing difficulties for the cabin crew. He was arrested on landing. On 30 March 1999, beginning at about 4pm, he consumed about ten pints of beer, about two small glasses of whiskey and three or four 250 ml bottles of 'Red Bull' over a period of about ten hours. Local beers contain 4 percent alcohol and whiskey about 40 per cent. At about 3.30 am on 31 March, he tried and failed to enter two houses. He succeeded at a third house by breaking down the front door and then ripping out the telephone wires. One of the occupants happened to be a newspaper columnist who wrote a detailed account in an Irish national tabloid newspaper (O'Toole, 1999). After a crazy monologue, claiming to be an American soldier in Kosovo and threatening the household, he was arrested by police. He was taken to the police cells and fell asleep. On waking in the morning, his last memory was of sitting in a nightclub bar. He had total amnesia for the rest of the night's events and was surprised when informed of his behaviour by the police. He linked this new experience to the consumption of the tablets and immediately discontinued. Prior to these episodes, he had no previous record of aberrant behaviour. It is possible but unlikely that the volume of alcohol consumed was sufficient to account for the amnesia.

About 36 hours after the amnesic episode, he was examined by a physician who found him mentally normal. A sample of urine was collected for analysis and stored frozen.

Urine analysis

An initial general drug screen was performed. Following addition of internal standard solution or water and pH11 buffer, basic drugs present in 1 ml of sample are extracted into 250 μ l n-butyl acetate and injected onto varian dual

column gas chromatography system (version 3400) by autosampler with nitrogen-phosphorus detection. The drugs content of the sample is determined by reference to urine spikes or to drug standard solutions. Both ephedrine pKa 9.6 and pseudoephedrine pKa 9.4 are weak bases. Caffeine has a pKa of 14. A test mix is then injected and evaluated. This contains 12 analytes and an internal standard. A second test mix including seven benzodiazepines is also used. If there is good peak shape then the samples are injected. Identification is by comparison of relative retention times using the custom made data base in folder. No caffeine or other drugs of abuse were present in the urine in the initial screening test.

The urine was also examined for amphetamine class drugs including MDMA (ecstasy). A two-step liquid-liquid extraction procedure followed by derivitization with heptafluorobutyric (HFB) acid for GCMS was used. The GCMS system consisted of a Finnegan Magnum ion trap which was run in Electron Impact mode using a SGE BPX 5 gas chromatography column with spitless injection. Identification of the ephedrine and pseudo-ephedrine in the sample was based on comparison of retention time and mass spectra with HFB derivatives of the corresponding reference standards. The sample was found to contain 22 ug/ml of ephedrine, and five pg/ml of pseudoephedrine.

A test for ethanol by head space GC using a Hewlett Packard 19395 system attached to a Hewlett packard 5790 was negative. All legal cases are extracted in duplicate.

Tablet analysis

Twenty 'vigueur fit' tablets were bought months after the last clinical episode. These were ground up and analysed in duplicate using a Shimadzu LC-10 system which consists of

a pump LC-10AS, autoinjector SIL 10A, diode-array detector SPD M10A, column oven CTO-10AC and a computing integrator (Dell OptiPlex GX1). GC-MS was carried out on a Varian 3800 GC with a Varian Saturn 2000 mass detector. The method was based on the British Pharmacopoeia (BP) 1999 method for pseudoephedrine tablets using a Sigma standard (lot 80H 5951). Standards for ephedrine hydrochloride, pseudoephedrine hydrochloride, methylephedrine hydrochloride and nor-ephedrine hydrochloride were also run and these analytes were not detected in the sample. A standard for norpseudoephedrine was not available.

Approximately 1 g powder from the 20 tablets was sonicated with 15 ml methanol and diluted to 25ml. The solution was filtered through a glassfibre filter (Whatman GF/C) followed by a 0.45 μ m Geiman Acrodisc and injected onto the HPLC. The retention times, in minutes, for the standards were 3.6 for norephedrine, 5.2 for ephedrine, 6.2 for pseudoephedrine, 8.2 for methylephedrine. All had characteristic spectra with maximum absorption at 252, 258 and 264 nm. A peak at 6.38 min was the only peak detected that had a characteristic ephedrine-like UV spectrum. Addition of pseudoephedrine standard enhanced the peak. Addition of ephedrine and norephedrine standards to the sample indicated that these were not present in the sample extract. There was no peak detected corresponding to the retention time of methyl-ephedrine. This indicated that only pseudo-ephedrine was detected.

The mass spectrum of the sample peak at 3.4 min showed a pattern characteristic of norpseudoephedrine, ephedrine and pseudo-ephedrine. The reference standards used for GC-MS were pseudoephedrine hydrochloride (1.0 mg/ml in methanol) and norephedrine hydrochloride (1.0 mg/ml in methanol). The

mass spectrum of norephedrine differed significantly. GC/MS does not distinguish between ephedrine and pseudoephedrine.

The mean tablet weight was 847.7 mg and the uniformity of weight complied with the B.P. specifications $\pm 5\%$; ie range 805.3–890.1 mg. Each tablet contained 7 mg of pseudoephedrine. Thus the daily dose of pseudoephedrine taken by this man was in the range 42 to 63 mg. There is uncertainty as to the dose of ephedrine consumed as the urine contained both ephedrine and pseudoephedrine but no ephedrine was detected in the tablet samples analysed.

Later, following a jury trial at the Circuit Criminal Court in Dublin, he was convicted of assault and trespass despite the medical evidence and fined £16,000. He was also tried for the air-line incident, found guilty and ordered to provide twice weekly urine tests for alcohol for six months.

DISCUSSION

Pseudoephedrine is a stereoisomer of ephedrine. Both ephedrine and pseudoephedrine exist in d- and l-forms (Bye *et al.*, 1974). The usual dose for the relief of nasal congestion is 60 mg every six hours in adults, a greater dose than that taken by this subject. A single oral dose of 60 mg pseudoephedrine produces a peak plasma concentration of 0.21 mg/L at three hours (Ellenhorn and Barceloux, 1988, pp.521-3). Both ephedrine and pseudo-ephedrine are well absorbed after oral administration. The half-life of pseudoephedrine in blood is seven hours. At a urine pH of 5.6, it is 1.9 hours but at urine pH of 7.4, it is 21 hours. It is excreted largely unchanged in the urine with less than 1 per cent excreted as the active metabolite norpseudoephedrine. There is no record of the urine pH in this case.

A study of urinary ephedrine excretion in healthy volunteers used six drops of commercial 0.75 per cent nasal solution instilled into each nostril four times at interval of two hours and the urine was collected each hour for ten hours. The total dose approximated to about 14 mg ephedrine. The urine ephedrine Values varied from 0.9 to 16.5 ug/ml. The percentage of the dose recovered in ten hours was 33 per cent (range 23-50%) and a negative relationship between excretion and urinary pH was confirmed (Lefebvre et al., 1992). The levels of ephedrine found in the urine and tablet analysis in this case are compatible with these study findings.

Pseudoephedrine and ephedrine are weak bases. They stimulate adrenergic receptors as well as releasing noradrenaline. Pseudoephedrine has less CNS and cardiac stimulant actions than ephedrine. The l-rotatory isomer of ephedrine is ten times more potent than the d isomer. Tachyphylaxis occurs with repeated use.

Ephedrine and pseudoephedrine are natural alkaloids and the exact constituents of alkaloid dietary supplements vary considerably depending upon where grown and the time of harvesting. As a consequence, there is a large batch to batch variation in samples of such products when tested (Gurley et al., 2000). Independent analytical information on between batch variation in the contents of 'vigueur fit' tablets is not available nor is it known whether the 'vigueur fit' tablets analysed were or were not identical to those consumed by the patient. However, it is likely that there was a difference as the patient's urine contained both ephedrine and pseudoephedrine despite the absence of ephedrine in the tablets analysed. It is also possible, but speculative, that another material containing ephedrine was ingested.

The stated contents of the tablets on the 'viguer fit' package insert are guarana extract, stearic acid, Siberian ginseng, MaHuang extract, white willow, getea kila, bladderwrack, astrogalas, licorice root, bee pollen, royal jelly, rehmannia root and chromium picolinate. Clinical effects from some of these substances are possible. Guarana is crushed seeds of *paullinia cupana varsorbilis*. The seeds contain 3-5 per cent caffeine as the major active ingredient. This has stimulant and appetite suppressant effects. Siberian ginseng has caused increased aggressive behaviour in animals and insomnia and nervousness in man, MaHuang is from ephedra species and may cause sympathomimetic toxic psychosis related to ephedrine. With chromium picolinate, there is a case report of a 35 year-old man with episodes of cognitive perceptual and motion changes with disruption of thought processes post ingestion which resolved within two hours (Huszonek, 1993). In a search of the Poison Index from Microdex (U.S.) used by the Irish Poisons Information Service at Beaumont Hospital, there was no entry for the other constituents of the "viguer fit" tablets listed above. According to Martindale, 29th edition (1989), *astregalus* (*laguminosae*) is a species of tree which produces a dried gummy exudation, obtained by incision of its trunk or branches. This is called *tragacanth*. It is a stabilizing and emulsifying agent used in the food industry. Royal Jelly, a milky white viscid secretion from the salivary glands of a worker bee is used as a general tonic but its therapeutic value has not been substantiated.

In the three years from 1994, the Food and Drugs Administration (FDA) in the U.S. has received more than 800 reports of adverse effects associated with the use of dietary supplements containing ephedrine alkaloids (Whitmore, 1997). The FDA suggested that labeling suggesting a daily total intake of 24 mg or more of ephedrine alkaloids should be

prohibited. This dose is a small fraction of that licensed for use in nasal decongestants.

Ephedrine-psychosis is well known and has often been reported with herbal dietary Supplements (Doyle and Kargin, 1996). Mania induced by ephedrine has also been reported (Capwell, 1995). Several deaths in the U.S. have been attributed to Ma Huang containing ephedrine (Josefson, 1996) and death and permanent disability related to ephedra alkaloids are still being reported to the FDA. There are no literature reports of psychosis with ephedrine in which drug levels have been quantified.

The clinical effects of ephedrine are markedly enhanced by caffeine. For example, in the treatment of human obesity, the ephedrine/ caffeine combination is effective. By contrast, each taken separately is ineffective (Astrup et al., 1992). The combination of caffeine and ephedrine may be fatal and in three such cases, the blood caffeine concentrations were 130-344 mF/L and the blood ephedrine levels were 3.5-20.5 mg/L (Garriott et al., 1985). This suggests a wide variation in dose response between patients. The urine ephedrine in one of these patients where measured was 238.9 mg/L.

Hailer and Benowitz (2000) were commissioned by the FDA to conduct an independent review of reports of adverse effects related to the use of dietary supplements that contained ephedra alkaloids. They found that estimated daily dose of ephedra alkaloids that caused death or severe disability varied from 20-66 mg. Thus the daily intake taken by the subject of this report was well up to these levels. Ephedrine at doses of 25 to 50 mg is used for bronchodilation. This indicates the unpredictability of adverse effects from ephedrine containing alkaloids. These effects are compounded by the pharmacological effects of caffeine which increase the effects

on the central nervous and cardiovascular systems by blocking adenosine receptors and augmenting the release of catecholamines (Robertson et al., 1978).

Whether other constituents of the 'vigueur fit' tablets could have added to the problem is unclear. Siberian ginseng usage has been associated with insomnia, nervousness and euphoria; however its toxicology is thought to be low (Martindale, 1989).

Red Bull is a stimulant drink which contains about 95 mg of caffeine and 1,000 mg of taurine per 250 ml. It also contains gluconolactone. There are about 30-120 mg of caffeine in a 140 ml cup of instant coffee. Caffeine is readily absorbed from the gut and peak blood levels occur from 45 min to two hours after ingestion. The half-life in normal adults is 3 to 7.5 hours. Smoking speeds caffeine clearance and the subject is a smoker. Adverse effects begin to appear at doses of 0.5 to 1 g of caffeine equivalent to about ten cups of coffee (Ellen-horn and Barceloux, 1989, pp. 508-14). The dose of caffeine taken in Red Bull was in the range 285 to 380 mg which of itself would be unlikely to have caused acute psychosis. Caffeine stimulates the central nervous system and in overdose, may lead to agitation, irritability and restlessness. Convulsions may occur. The half-lives of caffeine, pseudoephedrine and ephedrine are compatible with the laboratory findings. A report by the European Scientific Committee-on Food in 1999 concluded that there were insufficient data available to define upper-limits of dietary intake for taurine and gluconolactone (Birchard, 2000).

Assuming a body weight at that time of 88 kg, the patient's alcohol consumption of 10 pints of beer containing about 4 per cent ethanol by volume and 70 ml of whiskey at 40 per cent ethanol by volume would force the blood alcohol

to about 335 mg/dL. Alcohol intoxication may lead to loss of restraint and behavioural abnormalities. Levels of blood alcohol in the 180 to 300 mg/dl range lead to impairment of memory and comprehension and exaggerated emotional states of fear, anger and grief. Furthermore, the effects of alcohol may be enhanced by concurrent drug administration.

In January 2001, the Irish Medicines Board commissioned a review of alternative and herbal medicines to ensure their quality and safety (Barry, 2001). We echo the recent conclusion from a U.S. study that dietary supplements containing ephedrine alkaloids potentially pose a serious health hazard for some. Despite their use in conventional weight control studies at ephedrine doses of 60 mg daily (Toubro and Astrup, 1997), these tablets ought not to be available 'over-the-counter' and should be formally licenced (Fleming, 2000).

CONCLUSIONS

The admixture of ephedrine, pseudoephedrine and caffeine-containing weight reduction tablets with alcohol and caffeine-containing stimulant drinks may lead to serious adverse effects. We report an acute psychotic reaction caused by the interaction of ethanol, caffeine, ephedrine and pseudoephedrine which was short lived. The psychotic episode was witnessed by a journalist and immediately reported in a newspaper. Though consumption of these compounds is legal, it is in the public interest that ephedra alkaloids should be classified as a drug and not a dietary supplement. Persons taking ephedrine and caffeine combinations should refrain from the concomitant use of disinhibiting drugs such as ethanol.

ACKNOWLEDGEMENTS

We wish to thank Dr Liam Regan, State Laboratory, Abbotstown Dublin 15, Ireland for analysis of the urine sample.

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APPENDIX J

**IN THE UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF TENNESSEE AT
MEMPHIS**

Case No. 03-2121-Ma/V

<u>JOHN PARKER ROE,</u>)
Petitioner,)
)
v.)
)
JACK MORGAN, Warden,)
Respondent.)
<u></u>)

NOTICE OF EXHAUSTION OF STATE REMEDIES

Comes the Petitioner, John Parker Roe, by and through counsel, Douglas A. Trent, to give Notice that he has now exhausted state remedies on all of the issues in the Petition now pending before this Court. A copy of the Order of the Supreme Court of Tennessee denying application for permission to appeal is attached to this Notice. The Petitioner would ask this Court now to reopen this case and consider all of the issues he has presented to this Court in his Petition to vacate his judgment pursuant to 28 U.S.C. §2254.

Respectfully submitted,

/s/ Douglas A. Trant

Attorney for Petitioner

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(865) 525-7980

Signed in other than black ink for security purposes

CERTIFICATE OF SERVICE

I hereby certify that I have mailed or delivered a true and exact copy of the foregoing document to Elizabeth Mamey, Assistant Attorney General, P.O. Box 20207, Nashville, TN. 37202, on this the 20th day of September, 2004.

/s/ Douglas A. Trant

APPENDIX K

ARTICLE

- a statement of identity (product name) that identifies the product as a dietary supplement
- nutrition information in the form of a Supplement Facts panel
- a list of any ingredients not listed in the Supplement Facts panel
- the name and address of the manufacturer, packer, or distributor
- the net quantity of contents

In addition, if the labeling includes a claim that the product affects the structure or function of the body, a claim of general well-being, or a claim of a benefit related to a classical nutrient deficiency disease, the product must also bear a disclaimer stating that FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure, or prevent any disease. If a product that is marketed as a dietary supplement includes claims that the product is intended for the use in the diagnosis, cure, mitigation, treatment or prevention of a disease, it is considered a drug within the meaning of the Act.

DIETARY SUPPLEMENTS CONTAINING STEROID PRECURSORS

Because of the Committee's interest in steroid precursors, let me discuss them now. FDA is aware of a wide variety of products that contain steroid precursors. Some consumers ingest steroid precursors because they believe these products boost testosterone levels and speed muscle growth.

Use of these products has grown dramatically in popularity in the United States. We have heard from athletic organizations, health care professionals and health organizations, and anti-drug abuse authorities about potential health risks that may be associated with their use. However, the scientific evidence about the benefits or adverse consequences of steroid precursors appears to be inconclusive at this time. These products are generally marketed as dietary supplements and to athletes and body builders as performance enhancers. Some of these products are marketed for weight loss or as anti-aging products. While the majority of products containing steroid precursors are not promoted for disease treatment or prevention purposes, a minority of products may be promoted for therapeutic purposes and therefore are subject to regulation as drugs.

In addition, some steroid precursors are clearly outside the scope of the dietary supplement definition and are subject to regulation as drugs because they are intended to affect the structure or function of the body. For example, FDA considers tetrahydrogetrinone, or THG, the subject of what is rapidly becoming a major sports controversy, a new drug under FD&C. Our analysis demonstrates that this is a purely synthetic, non-naturally occurring, highly potent anabolic steroid. It is a designer steroid in the truest sense. It is directly derived, by simple chemical modification, from an

anabolic drug that is explicitly banned by the U.S. Anti-Doping Agency. That drug, gestrinone, a synthetic product, is approved in Europe for the treatment of endometriosis, a painful condition of pre-menopausal women. Furthermore, THG is closely related, structurally, to trenbolone, a strong veterinary anabolic steroid approved in the U.S. to increase rate of weight gain and/or improved feed efficiency in beef cattle. Trenbolone is a controlled substance.

Steroid precursors marketed as dietary supplements present complex regulation issues for FDA regarding the scope of the dietary supplement and drug definitions. FDA is still examining these issues and has not reached any formal conclusion about the status of steroid precursors as dietary supplements under the FD&C Act. Nevertheless, we understand that this is a public health issue that warrants our close attention. FDA is currently pursuing an evaluation of the legal and scientific uses that bear on the status of these kinds of substances and we hope to be able to address this matter more authoritatively in the future.

ADVERSE EVENT REPORTING

Now, let me turn to our discussion of dietary supplements. DSHEA's regulatory framework is primarily a post-market program, like much of food regulation. There is no pre-market approval requirement for dietary supplements. Further, there is no requirement for manufacturers to provide evidence of product safety to FDA prior to marketing a dietary supplement, unless the supplement contains a "new dietary ingredient" (a dietary ingredient that was not marketed in the United States before October 15, 1994) that has not been "present in the food supply as an article used for food in a form in which the food has not been chemically altered" (21 U.S.C. 350b(a)). In contrast, drug regulation involves explicit

standards of evidence. This evidence provides a basis to guide not only approval decisions but also conditions of use to manage benefits and risks. In addition, there are post-market reporting requirements for drugs to support product safety monitoring. These requirements do not exist for dietary supplements.

As a result, voluntary adverse event reports (AERs) are the primary means FDA has for identifying potential safety problems with dietary supplements. Under DSHEA, FDA must rely on AERs as a major component of its post-market regulatory surveillance efforts. Also, unlike drug regulation, FDA cannot compel reporting of adverse events by dietary supplement manufacturers.

In June 2003, FDA's Center for Food Safety and Applied Nutrition (CFSAN) put in place the CFSAN Adverse Event Reporting System (CAERS) to monitor adverse event reports for foods, cosmetics and dietary supplements. This state-of-the-art system compiles and analyzes any reports of consumer complaints and adverse events related to CFSAN-regulated products presented to FDA. Health care professionals and consumers voluntarily send submissions to CAERS. While voluntary reporting systems are estimated to capture only one percent of adverse events they provide valuable signals of potential problems.

ENFORCEMENT

Protecting the public health has always been the Agency's first responsibility. Consumers need to have confidence in the safety and effectiveness of the products they use. Therefore, unsafe, ineffective, or fraudulent products are a threat to the public health.

FDA is serious about its responsibility of ensuring that there is access to effective, safe, scientifically-based health products for our nation's citizens. U.S. citizens must have access to truthfully labeled, safe, effective, and non-misleading health products.

At the core of FDA's enforcement effort is our commitment to enhance the legal manufacture, sale, and use of dietary supplements while protecting consumers against unsafe products, fraudulent labeling claims, and other illegal practices. Achieving these goals utilizes a number of strategies, including cooperation and coordination with other state, Federal, and international law enforcement agencies in protecting consumers against unapproved and potentially harmful products offered by Internet outlets, some of which are based abroad.

On December 18, 2002, FDA announced its "Better Health Information for Better Nutrition" initiative. The purpose of the initiative is to improve the health of consumers by providing them with scientifically accurate, FDA-approved information about the health effects of foods and dietary supplements. In undertaking this initiative, FDA recognized that false claims that mislead Americans both endanger the public health and undermine the goals of the FDA. Because FDA recognizes that efficient enforcement is an essential component to ensure that such false and misleading claims do not take root in commercial distribution channels, FDA is prepared to take aggressive enforcement action to ensure that consumers have access to truthful and non-misleading information about products related to their health.

FDA's commitment to continue its efforts to ensure that there is access to safe, scientifically sound medical products is demonstrated by the Agency's enforcement actions to

combat fraudulent, misbranded, and misleading dietary supplements. For example, over the last 15 months, FDA has witnessed the voluntary destruction of approximately \$7.7 million of dietary supplements that were determined to be non-compliant with the FD&C Act and has monitored two voluntary recalls of dietary supplement products.

FDA also sent numerous Warning Letters to marketers of products represented as dietary supplements but whose products did not qualify as such because claims on them caused them to be misbranded and/or unapproved drugs. At least two of these Warning Letters were sent to firms whose products were marketed in lieu of approved drugs that were available to the public. For example, one made claims that its products were alternatives to vaccinations/immunizations against anthrax, measles, smallpox, and encephalitis; the other promoted its product as a natural alternative to Ritalin for ADHD. This calendar year, FDA also issued Warning Letters to 18 firms marketing coral calcium products as effective treatments or cures for a variety of disease conditions. In addition, FDA and the FTC warned website operators, manufacturers, and distributors who were making misleading or deceptive claims on the Internet regarding their products ability to prevent, treat, or cure SARS that they must cease making these impermissible claims. FDA also issued Warning Letters to 8 firms marketing "dietary supplements" as street drug alternatives and warned 26 firms to stop making unproven claims that ephedrine-containing dietary supplements could enhance athletic performance.

Lastly, over the course of the course of the last 15 months FDA utilized its judicial and administrative enforcement tools to take one injunction action and 8 seizure actions against marketers of and/or fraudulent dietary supplements. Six of the

seizure actions occurred in FY 2003 alone, including 3 that were undertaken in cooperation with FTC.

Health Fraud

Traditionally, FDA has taken action against violative dietary supplements as part of its health fraud efforts. Generally, FDA defines health fraud as the deceptive promotion, advertising, distribution, or sale of articles that are represented as being effective to diagnose, prevent, cure, treat, or mitigate an illness or condition, or provide a beneficial effect on health where the product has not been scientifically proven safe and effective for such purposes.

The Internet is one avenue by which fraudulent products have been promoted. The use of the Internet by our nation's citizens, from school age children to seniors, has opened up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest academic health centers. The Internet also permits an increasing number of individuals to obtaining meaningful medical information that helps them understand health issues and treatment options. As beneficial as this technology can be, it also creates a new marketplace for activity that is illegal, such as the sale of unapproved new drugs, prescription drugs dispensed without a prescription, and products marketed with fraudulent claims about health benefits. Also, because the Internet is a worldwide communications system, U.S. citizens are now more directly susceptible to fraud from sources both foreign and domestic.

Consumers respond to these promotions by spending billions of dollars a year on fraudulent health products. They hope to find a cure for their illness or improve their well-being or appearance. Yet, consumers often fall victim to products and devices that do nothing more than cheat them out of their money, steer them away from useful proven treatments, and possibly do more harm than good.

FDA Web Site Triage Process

In June 1999, FDA established a case assessment or "triage" team with representatives from the Offices of Criminal Investigation within the Office of Regulatory Affairs, the Center for Drug Evaluation and Research, the Office of Chief Counsel, and the Office of Policy. The scope of this group has been expanded to cover all FDA Centers and regulated products including the CFSAN's Office of Nutritional Products, Labeling and Dietary Supplements.

Under the triage process, FDA identifies web sites that potentially violate the FD&C Act from the Agency's Internet monitoring activity, other Federal or foreign law enforcement agencies including our joint partnership with the Federal Trade Commission (FTC), and from states and the public. The Triage team evaluates each case to determine whether or not it should be pursued through a civil or criminal investigation. Using this information, we give priority to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription, and products with the potential for causing serious or life-threatening reactions.

This triage process results in improved coordination of criminal and civil enforcement actions within the Agency, reduces overlapping efforts, and helps the Agency

appropriately achieve a maximum deterrent effect when taking action to remove harmful products from the market.

Oversight of Dietary Supplements

FDA shares Federal oversight of dietary supplements with the Federal Trade Commission (FTC). FDA regulates the safety, manufacturing, and labeling of dietary supplements, while FTC has primary responsibility for regulating the advertising of these products. Over the last few years, the FDA and the FTC have worked well together to ensure that there is a seamless assertion of our jurisdiction over these products.

As with all of FDA's activities, priorities are established based on benefit/risk to public health. The Agency's enforcement of fraudulent health products is based on a priority system that is often driven by whether a fraudulent product poses a direct or indirect risk to public health. The susceptibility of the population is also an element that we consider when determining risk. For example, cancer patients are considered a highly susceptible population, as many have exhausted conventional or standard care treatments, and may be desperate to try anything that offers hope of a cure.

Products that present a direct health hazard to consumers are the Agency's highest priority. These are products that have a reasonable potential for causing direct serious adverse effects, or for which there is documentation of injury or death. When the Agency encounters such products, FDA will use all available civil and administrative remedies to assure that the product is quickly removed from the market. We also aggressively publicize our actions to warn consumers and health professionals about such products. In some cases, the agency may initiate a criminal prosecution.

Products that are not themselves hazardous can still present an indirect health hazard in that the consumer may delay or forego proven medical treatments or drug therapies, or rely on these products for benefits that simply are never going to materialize. Examples include unproven products promoted for the treatment of cancer, Alzheimer's disease, arthritis, heart disease, and high blood pressure.

In addition to these direct and indirect health risks, we also give priority to products that undermine the integrity of the new drug application (NDA) and Over-the-Counter (OTC) drug review processes. The NDA and OTC drug review procedures provide consumers with assurance that prescription and OTC drugs are both safe and effective. To avoid undermining these procedures, it is essential for FDA to maintain vigorous surveillance, provide prompt industry guidance and outreach, and take enforcement action regarding fraudulent products. Such actions help ensure that manufacturers comply with the requirement to submit an NDA to the Agency for their product and that the playing field is fair and equitable for those who do.

Initiation of Enforcement Activity

When a problem arises with a product, or the Agency receives information that a product may violate the FD&C Act or regulations, FDA can take a number of enforcement actions to protect the public. For example, FDA may initially work with a product's manufacturer or marketer to correct the problem voluntarily. If that fails, the Agency may bring a lawsuit to seize the product and/or enjoin the firm marketing or distributing the product. When warranted, FDA may also seek criminal penalties, including prison sentences, against parties who break the law.

In the appendix attached to my testimony, I describe some of FDA's recent dietary supplement enforcement activities. As you will see our enforcement actions are wide-ranging and diverse and take full advantage of the entire breadth of enforcement tools that are available to FDA. You will also see that the type of cases that we have brought have evolved over time. We hope that they also illustrate to the public and the industry that we will take action when warranted, and that FDA also remains committed to consumer and industry education about the proper labeling and use of dietary supplements.

Outreach and Education

FDA recognizes that traditional enforcement actions and coordinated efforts with other agencies are necessary, but these steps are not the only components of a thoughtful enforcement strategy. We fully appreciate that the dietary supplement industry has a vested interest in curbing fraudulent operators and practices and that most of FDA's regulated industries are interested in complying with operators and practices and that most of FDA's regulated industries are interested in complying with the Act- and do so. For this reason, FDA will continue in its effort to complement these measures with industry and consumer education and will continue to assist the industry by issuing regulations and guidance documents addressing the manufacture, labeling, and sale of dietary supplements.

Examples of prominent FDA outreach activities in this area include:

- continuing to develop mechanisms, including expanded use of our Web site, to communicate critical information and useful strategies about dietary supplements to industry

and consumers. Coordination with groups like the Better Business Bureau, and with professional groups like the American Medical Association, will help FDA to reach the broadest possible audience;

- continuing to encourage consumers to involve their health care practitioners in their health care decisions. Ultimately, however, consumers must be able to evaluate the accuracy of labeling supplements, and with the assistance of health professionals when appropriate, are right for them. Accordingly, through written materials and Web-based resources, FDA has provided consumers with the means to make informed choices about dietary Supplements. Examples include FDA Talk Papers, articles in the *FDA Consumer* magazine, and information on FDA's web site to educate consumers about safely purchasing FDA regulated products. Other examples of these material include CFSAN's "Overview of Dietary Supplements" and "Tips for Savvy Supplement User." CFSAN has also published consumer advisories concerning dangerous products, such as the advisory that the Agency issued about dietary supplements containing kava, a botanical ingredient:
- continuing to communicate with industry regarding those practices that are permissible under DSHEA. We will continue our practice of providing this information through guidance documents and information posted on the Agency's web site. For example, FDA's "Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide" discusses compliance with the Agency's regulations implementing DSHEA's labeling provisions; and

- **leveraging resources by continuing to coordinate mutually effective relationships with other Federal and state entities involved in combating health fraud.** For example, in 1992, FDA began sponsoring a National Health Fraud Working Group. This working group is comprised of representatives from the Association of Food and Drug Officials, State Attorneys General, FTC, Health Canada, and FDA representatives from headquarters and field offices. The group meets on a regular basis to facilitate the to facilitate the coordination of regulatory activities, information exchange, and leveraging the efforts of each member agency.

Partnership with Federal Trade Commission (FTC)

As discussed earlier, FTC and FDA have a long standing history of working together to combat health fraud. This partnership was formed out a recognition that although protection of the public health may be FDA's primary goal, other can contribute to achieving this goal. To further their mutual interest in consumer protection, FDA and FTC formed a Dietary Supplement Enforcement Group to closely coordinate their enforcement efforts against health care fraud. A major activity includes Operation Cure-All, which is aimed at halting the Internet promotion of products, including dietary supplements, that make false or misleading disease claims In addition FDA and FTC chair an Interagency Health Fraud Steering Committee that meets regularly to coordinate activity on these issues. The workgroup includes Federal agencies in the U.S. and Canada, and Mexico also has been invited to join the group. As part of its effort to curb internet health fraud, FDA has conducted several "surfs" to identify fraudulent marketing of health care products over the Internet. These actions were carded out in partnership with the FTC and other law enforcement and public health authorities in the

U.S. and abroad. These efforts have led to many successful actions that have protected the public health. Together, we have succeeded in accomplishing goals that neither one of our agencies could accomplish individually.

DIETARY SUPPLEMENTS CONTAINING EPHEDRINE ALKALOIDS

A number of plant genera, including ephedra, are known to contain ephedrine alkaloids. Ma Huang is a common name given to Chinese Ephedra, which is used in traditional Chinese medicine. Ephedra has been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine, phenylpropanolamine and norpseudoephedrine, as well as various tannins and related chemicals. The concentrations of these alkaloids depend upon many factors, such as the species, parts of the plant used, time of harvest, growing location, and production methods. Ephedrine and pseudoephedrine are used in some OTC and prescription drugs, where they have been demonstrated to be safe and effective for the labeled use.

Dietary supplements containing ephedrine alkaloids have known, and potentially serious, side effects. While ephedra has been used in herbal medicine preparations for thousands of years, in recent years ephedra has been sold primarily in dietary supplement products for weight control, as well as in products promoted to boost energy levels or to enhance athletic performance. Some ephedra containing products have been marketed as herbal alternatives to illicit street drugs. Ephedra-containing products often contain other stimulants, such as caffeine, that may have synergistic effects and increase the potential for adverse effects.

A number of adverse effects associated with ephedrine alkaloid-containing dietary supplements have been reported to FDA. These include elevated blood pressure, rapid heartbeat, nerve damage, muscle injury, psychosis, and memory loss. More serious effects have also been reported, including heart attack, stroke, seizure, and death.

As the tragic deaths of the Baltimore Orioles' pitching prospect Steve Bechler and of Sean Riggins, the sixteen year-old from Illinois have reminded us that use of ephedra, particularly in sports, raises serious concerns about safety and has long posed difficult issues for health care professionals, regulators, and consumers. These concerns stem from both the mechanism of action of ephedrine alkaloids on the sympathetic nervous system, and accumulating evidence of potentially serious adverse events after use of ephedra-containing products.

While there has been considerable debate about the safety and effectiveness of dietary supplements like ephedra, as well as the most effective approach to regulation them, one thing is clear: although dietary supplements are regulated as foods and not drugs, the consumer should not assume they are always safe to use. "Natural" does not necessarily mean safe. In particular, botanical and herbal products may have active ingredients with pharmacologic properties similar to , or in the case of ephedra identical to, drug products. They have the potential to cause adverse effects, as well as interactions with prescription and OTC drugs and with ingredients in other dietary supplements.

USE OF EPHEDRA BY ATHLETES

Although FDA is reviewing ephedrine alkaloids under DSHEA to assess the safety concerns, FDA has particular

concerns about the use of ephedra by persons engaged in strenuous exercise. A recent study by RAND, discussed in more detail below, concluded that ephedra has minimal if any proven benefit for enhancing sports performance. Yet ephedra acts like an adrenaline boost, stressing the heart, raising blood pressure, and increasing metabolism. Moreover, the stimulating effects of ephedra may mask the signs of fatigue, causing even the most well conditioned athletes to push beyond their physical limits. Thus, ephedra's risks are potentially much more serious for competitive athletes than for the general population. As FDA has said before, ephedra should not be used by people who engage in strenuous activity.

Because of the special risks of ephedra use in athletes, sports leagues that have acted to restrict ephedra use are making a prudent decision. Even as the Agency evaluates the safety of ephedra use in the population more generally, including its use for weight loss, we see that ephedra poses special risks in the context of sports performance with little or no identified benefit for athletes.

FDA'S ACTIONS ON EPHEDRINE ALKALOIDS

The Agency's professional, scientific and legal staffs are currently working hard to address the extraordinary challenges presented by these products. Earlier this year, the Agency published a Federal Register notice reopening the comment period on its 1997 proposed rule on dietary supplements containing ephedrine alkaloids to seek comment on new scientific evidence about the risks of these products and on a proposed warning statement for the labels of these products. Our *Federal Register* announcement also sought comments on whether, in light of current information, FDA should determine that dietary supplements containing

ephedrine alkaloids present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or under ordinary conditions of use if the labeling is silent.

We are currently in the process of analysing the over 30,000 public comments we received earlier this summer as well as adverse event information and the best available scientific evidence of ephedra's pharmacology and mechanism of action. We are in the final stages of our deliberative review, so I cannot discuss the specifics of that process or the anticipated outcome. However, I want to emphasize that we are committed to moving forward expeditiously to make a determination that is well grounded in all available scientific evidence and that is protective of the public health in accordance with DSHEA.

While we are undertaking these reviews, the Agency has dramatically increased its enforcement actions against ephedrine alkaloids and other dietary supplement products making false or misleading claims. These actions, many of which have been undertaken in collaboration with the FTC, are having an impact on the marketing of dietary supplements in general and ephedra in particular.

Sports Uses of Ephedra

On February 28, 2003 based on the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary supplements enhance athletic performance. The actions were primarily a result of the Agency's surveillance of the firms' web sites. Fourteen of the firms responded to the warning letters by discontinuing the product or the claim. The remaining twelve firms were inspected by FDA. Of those

twelve inspected firms, all but one either discontinued the product or the objectionable claims. Investigation for consideration of regulatory action against the remaining firm is ongoing. Since performance enhancement was one of the two principal ways in which ephedra has been marketed, the impact of these warning letters has been substantial. FDA continues to monitor the compliance of products on the Internet.

DIETARY SUPPLEMENT CURRENT GOOD MANUFACTURING PRACTICES

Another important aspect of FDA's regulatory and surveillance programs is to help ensure that dietary supplements are manufactured in a manner that will not result in adulteration. DSHEA gave FDA the authority to promulgate regulations for dietary supplement current good manufacturing practices.

On March 13, 2003, FDA published a proposed rule to establish CGMPs for dietary supplements. FDA's proposed rule, if finalized as proposed, will give consumers greater confidence that the dietary supplements they choose to use will have the identity, strength, purity, quality or composition claimed on the label. The CGMPs will help prevent product quality problems such as superpotency, subpotency, contamination, improper packaging, and mislabeling.

The proposed rule would:

- include requirements on the design and construction of physical plants, to facilitate maintenance, cleaning, and proper manufacturing operations;

- include requirements for production and process controls with the use of a quality control unit in the manufacturing, packaging and label operations;
- include requirements for product testing and handling of consumer complaints; and
- apply to all firms that manufacture, package, or hold dietary ingredients or dietary supplements, including those involved with testing, quality control, packaging, labeling, and distribution. The proposed regulations also would apply to both domestic and foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements for distribution into the U.S.

The public comment period on this proposed rule closed on August 11, 2003. The Agency is carefully reviewing all of the comments.

Mr. Chairman, thank you for this opportunity to testify. I am happy to answer your questions.

FOOTNOTES:

¹ Bennett, J. and CM Brown. 2000. "Use of Herbal Remedies by Patients in a Health Maintenance Organization." *Journal of the American Pharmaceutical Association*. Volume 40, Number 3: 353-358.

² *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. File Inventory, Evidence Report/Technology Assessment Number 76. AHRQ Publication No. 03-E022, March 2003. Agency for Healthcare Research and Quality, Rockville, Maryland.

³ *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. File Inventory, Evidence Report/Technology Assessment Number 76. AHRQ Publication No. 03-E022, March 2003. Agency for Healthcare Research and Quality, Rockville, Maryland.

Enforcement Strategies Used to Enforce DSHEA

Inspections That Resulted in Voluntary Compliance

- in October 2003, FDA witnessed the voluntary destruction of Royal Tongan Limu, a liquid dietary supplement distributed by NBTY, Inc., in Murphysboro, Illinois. This destruction concluded a series of Agency actions that started with the Issuance of a Cyber Letter to Dynamic Essentials of Lake Mary, Florida for health claims associated with the product that were made on the firm's website. Subsequent follow up revealed that Dynamic Essentials was a subsidiary of NBTY, and that the product was being distributed from NBTY's Illinois location. Even after the issuance of the Cyber Letter, the product remained in distribution channels and, therefore, FDA recommended a seizure action. However, in lieu of seizure, the firm chose to voluntarily destroy its inventory of approximately 90,000 bottles of Royal Tongan Limu, along with the product's related literature and materials. Approximately 188 tons of material was destroyed with an estimated value of \$2.7 million.
- On April 30, 2003, Nature's Youth, LLC, of Centerville, Massachusetts, voluntarily destroyed approximately 5700 boxes of its misbranded product, "Nature's Youth HGH." This destruction occurred at locations in Massachusetts and Florida, and involved approximately \$515,000 worth

of the product. The firm's action was the result of an FDA advisory that the products appeared to be misbranded by virtue of unsubstantiated "structure and function" statements that claimed that the product would, among other things, "improve physical performance, speed recovery from training, increase cardiac output, and increase immune functions." The product also claimed to be "your body's best defense against aging."

- In January, 2003, FDA and the U.S. Marshal's Service served an inspection warrant that would allow FDA to witness the voluntary destruction of \$4 to 5 million worth of products known as "Yellow Jackets" and "Black Beauties." The warrant was served at NVE Pharmaceuticals, the manufacturer of the products, located in New Jersey. A distributor in the Netherlands promoted the products on the Internet as alternatives to street drugs. Yellow Jackets and Black Beauties are "street terms" for controlled substances and were sold as herbal street drug alternatives. In September 2002, FDA became aware of the tragic death of a 16 year-old high school football player who had taken Yellow Jackets. FDA placed the products on Import Alert on October 7, 2002. An attempt by FDA to inspect the manufacturer of the products on October 8, 2002, resulted in an inspection refusal, forcing FDA to obtain an inspection warrant. FDA obtained an additional inspection warrant in January 2003. After NVE stopped marketing Yellow Jackets and Black Beauties, it began marketing "Yellow Swarm" and "Midnight Stallion" as replacement products. Although these products appear to be almost identical in formulation and appearance to the previous products, they no longer bear street drug names or claims.

- FDA conducted a May 2002 inspection of Fresh Vitamins, a manufacturer of Noni Fresh Juice. Fresh Vitamins marketed its product to treat conditions ranging from immune system disorders to arthritis, malaria, and alcohol addiction. Following the inspection, the firm's president stated that he had removed impermissible claims from the firm's website and that he was educating himself on FDA policy regarding dietary supplement claims.
- Following a May 2002 inspection of Health Ventures, a manufacturer of Miracle Bust, a FDA investigator witnessed the destruction the company's inventory. The company signed an affidavit stating that it would voluntarily stop the sale and distribution of Miracle Bust, delete references to it on its website, and refrain from placing future orders from its contract manufacturer.

Voluntary Recalls

- On May 23, 2003, Best Life International, Mayaguez, Puerto Rico, issued a voluntary recall and warned consumers not to buy or consume its product caged Viga. Viga, marketed as a dietary supplement, was found to contain sildenafil, the active ingredient in Pfizer's Viagra. Sildenafil can cause life-threatening lowering of blood pressure when taken with nitrates.
- On February 11, 2003, Best Life International recalled Ancom Anti-Hypertensive Compound tablets. Although these products claimed to be dietary supplements, they were found to contain several prescription drug ingredients, including reserpine, diazepam, promethazine, and hydrochlorothiazide. The product was sold on the Internet and at retail stores.

- On September 30, 2003, FDA issued a Warning Letter to Dr. Gordon Joseph, Chelationcare Centers U.S.A., Scottsdale, Arizona. Dr. Joseph's website, <http://www.anti-thrax.com> and <http://www.homevax.com> marketed an anthrax vaccine alternative and viral immune alternative immunizations and vaccinations. The anti-anthrax vaccine contained *Bacillus anthracis* and other ingredients that are recognized in the Homeopathic Pharmacopeia of the United States (HPUS). The "Viral Immune" product made claims that it was a defense against smallpox, measles, and encephalitis viruses. These statements, and the therapeutic claims establishing the intended use of the products, caused them to be misbranded drugs.
- A Warning Letter was issued to Michael Peng, President of Greenvally, LLC, located in Farmingdale, New York on September 26, 2003, for offering trans-dermal products intended for the treatment of diabetes and prostate disease-related symptoms via a website, <http://gyconline.com>. Moreover, although the products were marketed as dietary supplements, they did not qualify as dietary supplements since they were not intended for ingestion as set forth in the Act. Additionally, FDA had no information to indicate that the products were generally recognized as safe and effective for their intended use; and the products were misbranded because they failed to bear adequate directions for use.
- On July 22, 2003 FDA issued a Warning Letter to Ayoula Dublin, New York, New York, for marketing and distributing "Lipostabil," and injectable product that claimed to break down and dissolve fat "for the person who wants to lose those last 5-10 extra pounds." Although the product claimed to be a dietary supplement,

its route of administration disqualified it as a dietary supplement (since it was not intended for ingestion). Moreover, the product's structure/function claims and lack of substantiation to show that the product was generally recognized as safe and effective for its intended use made it a new drug without an approved drug application.

- On June 9 and 10, 2003, FDA issued Warning Letters to 18 firms that operated 24 websites marketing multiple coral calcium products as effective treatments or cures for a variety of diseases and conditions. Many of these coral calcium products also made unsubstantiated structure/function claims. Coral Calcium Supreme was promoted in nationally televised 30-minute infomercial featuring Keven Trdeau and Robert Barefoot on cable channels such as Discovery Channel, Comedy Central, and Bravo.
- On March 31, 2003, FDA sent Warning Letters to 8 firms after an investigation revealed that the firms sold "street drug alternative" products marketed for "recreational" purposes with claims that they would produce such effects as euphoria, a "high," or hallucinations. These street drug alternatives cannot meet the legal definition of a dietary supplement because they are not intended to supplement, the diet. The 8 letters were targeted primarily to manufacturers of products that contained ephedrine or norephedrine hydrochloride and whose products were labeled as dietary supplements for use in weight loss, suppression of appetite, and enhanced libido.
- On February 28, 2003, based upon the conclusions of the RAND study, FDA warned 26 firms to cease making unproven claims that ephedrine-containing dietary

supplements enhance athletic performance. These warnings were issued primarily as a result of the Agency's surveillance of the firms' websites. Fourteen of the firms responded to the Warning Letter by discontinuing the violative products and/or fraudulent claims. FDA inspected the twelve remaining firms. Since performance enhancement is one of the two principal ways in which ephedra products have been marketed, the impact of these Warning letters was substantial. FDA continues to monitor the firms/websites/products to ensure their compliance with applicable regulations.

- In August 2002, FDA issued a Warning Letter to Better Way Kids. This firm distributed "Calm Focus" a product promoted to treat Attention Deficit Disorder and Hyperactivity Disorder. The firm characterized its product as a "natural alternative to Ritalin" and claimed that it was "formulated to energize neurotransmitters in the brain." The Warning Letter made clear that dietary supplements may not make disease claims or unsubstantiated structure/function claims. The firm corrected its product claims.

In mid June, 2002, FDA sent seven Warning Letters to manufacturers of products containing synthetic ephedrine.

- In 2002, the Agency issued 17 Dietary Supplement Warning Letters, with products containing synthetic ephedrine receiving particular attention. Marketers promoted these products for use in weight loss, energy enhancement, and to increase libido. However, the presence of synthetic ephedrine placed the products outside the definition of a dietary supplement.

Seizures and Injunctions

- On September 22, 2003, a U.S. District Court Judge entered a Consent Decree of Permanent Injunction enjoining Hi-Tech Pharmaceuticals, National Urological Group, National Institute for Clinical Weight Loss, American Weight Loss Clinic, United Metabolic Research Center, and the President of these corporations, from distributing unapproved new drugs and misbranded drugs. Despite FDA's warnings, the defendant and his related businesses repeatedly sold dietary supplements that claimed to treat obesity and erectile dysfunction. Earlier in June 2003, FDA had issued a "Public Health Alert" warning consumers not to purchase or consume certain dietary supplements sold by Hi-Tech Pharmaceuticals, Inc., and related businesses because FDA test results had found that the supplements were adulterated with the prescription-strength drug ingredient tadalafil. An interaction between certain prescription drugs containing nitrates (such as nitroglycerin) and tadalafil could cause a drastic lowering of blood pressure. The possibility that patients who did, indeed, take nitrates could have consumed the supplement was very real since erectile dysfunction is often a common problem in people who have diabetes, hypertension, high cholesterol, and heart disease.
- On September 18, 2003, at FDA's request, the U.S. Marshal seized herbal tea products known as Forticel and Forticel Mix from Jean's Greens in Norway, New York. The products claimed to treat and cure various life-threatening and serious illnesses, such as cancer, which caused them to be unapproved drugs. FDA had warned Jean's Greens in November 2001, to change its labeling for the products, but it did not comply. The seized goods,

which included 385 bottles and 78 mix packages, were worth more than \$4,000.

- On June 18, 2003, the U.S. District Court for the Southern District of Florida entered a Consent Decree of Condemnation and Destruction for 450 bottles and 57,000 bulk capsules of dietary supplement products seized by U.S. Marshals at Global Source Management and Consulting, Inc. (Global Source), located in Sunrise, Florida, on February 13, 2003. The seizure occurred after FDA determined that these products claimed to treat a variety of medical conditions, causing them to be drugs. The seizure included almost 20 different products worth nearly \$19,000 that were sold under the names Vitamin Hut and RX for Health through retail outlets and by mail order. Under the terms of the Consent Decree, the Claimant, Global Source, had to destroy all of the products. In addition, Global Source agreed to cease manufacturing, processing, packing, labeling, holding, or distributing "Vitamin Hut Scientific Cholesterol Support Program" or any similar red yeast rice product containing lovastatin or any other drug product that is a new drug unless and until an approved new drug application is in effect for such product.
- On December 16, 2002, U.S. Marshals seized approximately 3,000 bottles of EverCLR was marketed by Halo Supply Company of San Diego, California a "natural" treatment for viruses such as herpes and "cold and flu protection." None of these claims had been substantiated. FDA charged that EverCLR was an unapproved and therefore, illegal, new drug because it was promoted to treat and prevent specific diseases and conditions. Because EverCLR's labeling lacked adequate directions for use, FDA also charged it was misbranded.

- In the summer of 2002, FDA filed two seizure actions against dietary supplements making unsubstantiated claims about their effect on the structure or function of the body.
 - United States v. Undetermined Quantities of Casas of an Article of Food and Drug Labeled in Part: Brain Nutrient Capsule, involved a product offered as a supplementary treatment for mental retardation, cerebral palsy, and epilepsy. The product's distributor claimed that it "has the function of increasing the intelligence, elevat[ing] the intelligence quotient (IQ) and promoting growth.." FDA alleged that these claims were baseless.
 - United States v. 172/100 Capsule Bottles, More or Less, of an Article of Food Labeled in Part: Kirkman Taurine 325 mg Dietary Supplement Capsules, concerned a product offered as a supplementary treatment for autism. Materials promoting the product stated, "Dr. Jeff Bradstreet, a physician in Palm Bay, Florida, who treats autistic patients reports good success using Taurine." The materials further asserted that "[t]aurine may be beneficial in developmental disorders." FDA alleged that there is no scientific support for these claims.
- In March, 2002, FDA seized products marketed as dietary supplements that contained synthetic ephedrine. For example, United States v. 1009 cases et al, involved the seizure of nearly \$3 million worth of Amp II Pro Drops from a company doing business as E'OLA international. Although labeled as s Supplement, the product contained synthetic ephedrine. FDA alleged that the product violated

the law because synthetic ephedrine is not a dietary ingredient. Accordingly, a product containing synthetic ephedrine is not a dietary supplement. The Agency also alleged that the product which was marketed to treat obesity, made illegal disease claims. The consent decree required the product's destruction and prohibited E'OLA from manufacturing or distributing products that violate the FD&C Act.

- In 2001, FDA brought a seizure action against a purported supplement manufacturer that marketed its products as illegal street drugs. The case, U.S. v. Undetermined Quantities of Articles of Drug, Street Drug Alternatives...et al. Showed that Hit Products Inc., and Organic Diversions, Inc. Marketed products made from a mixture of herbs that promised users effects comparable to illegal street drugs. FDA categorized these products as "street drug alternatives" and seized them as misbranded and unapproved new drugs in violation of FD&C Act. FDA sought the destruction of the seized goods and an injunction barring defendants from future FD&C Act violations. In granting this relief, the court found FDA's position on street drug alternatives "highly persuasive" and criticized the defendants' characterization of the products as dietary supplements as a "veiled attempt to circumvent" the FD&C Act. The court decline[d] to carve out a statutory loophole for drug manufacturers attempting to profit from the illegal drug epidemic by masquerading potentially dangerous substances as dietary supplements."
- In 2001, FDA's injunction actions also extended to supplement marketers who violated DSHEA's proscription of disease claims. Samples include:

- U.S.v. Lane Labs USA, Inc. and Andrew Lane constituted an injunction action that involved several of Lane Labs' products, including its shark cartilage product. Lane Labs marketed this product as a dietary supplement, but made unsubstantiated cancer treatment claims about it. FDA contended that the disease claim caused the product to be an unapproved, and therefore illegal, new drug.
- U.S.v. Syntrax Innovations, Inc., et al. involved a drug called Triax Metabolic Accelerator, marketed by Syntrax as a dietary supplement for the treatment of obesity and to promote weight loss. FDA scientist determined that the product contained tiratricol, a hazardous compound that can cause heart attacks and strokes. FDA alleged that Triax could not be a dietary supplement because it was promoted to treat disease (obesity) and because it did not contain any of the dietary ingredients identified in DSHEA. In February 2001, the court entered an injunction barring the distribution of Triax.

Criminal Enforcement

- As a result of concurrent federal search warrants executed by OCI in Georgia and New Jersey. FDA warned consumers on June 20, 2003, not to purchase or consume Sigra, Stamina Rx, and Stamina Rx for Women, Y-Y, Spontane ES, and Uroprin. These products, which were marketed as dietary supplements, contained a prescription drug ingredient, tadalafil, which posed health risks when taken with certain prescription drugs containing nitrates. Tadalafil is the active ingredient in Cialis, an Eli Lilly product approved in Europe to treat male erectile dysfunction. The products were being sold over the

counter and claimed to increase stamina, confidence, and performance. (A civil, permanent injunction was also filed– see description under Seizures/Injunctions.)

- In U.S. v. Cap-Tab Nutritional Formulatine and Manufacturing Inc., an officer of a corporation known as Cap-Tab, along with the corporation itself, was convicted in June 2002 of one count of introducing misbranded food into interstate commerce. This case stemmed from an allegation that three individuals who were all officers of Cap-Tab conspired and knowingly substituted low-price ingredients for the ingredients listed on the label of their dietary supplement product (encapsulated vegetable powders.) Three of the defendants in the case received sentences of one year's probation and were ordered to pay fines of \$500, \$250, and \$5000, respectively. A fourth defendant received a sentence of 180 days' incarceration followed by five years' incarceration on a related state criminal conviction.
- In U.S. v. Diane Eckert-Kunick, an individual was convicted in April 2002 of introducing unapproved new drugs into interstate commerce and subsequently received a sentence of four months' incarceration in a community correctional center. The defendant, along with her parents, had fanned a company known as New Gala Products (NGP) in 1996. The company manufactured, distributed, and sold dietary supplements including colloidal gold, colloidal silver, and colloidal titanium. The defendant also distributed promotional literature claiming that NGP products cured cancer, rheumatoid arthritis, and heart disease.
- In U.S.v. Theodore Sosangelis and Thomas Knox, two individuals pled guilty in October 2001 and February

2002, respectively, to trafficking counterfeit dietary supplements in interstate commerce. From January through July 2000, via their company, East Coast Ingredients, the defendants produced inexpensive versions of legal supplements manufactured by Muscletech. After placing fake Muscletech labels on their products, the defendants sold them to customers who believed that they were purchasing legitimate Muscletech dietary supplements. One of the defendants in the case received a sentence of three years' probation and was ordered to pay restitution of almost \$77,000.

- FDA determined that the pre-DSHEA product known as Nature's Nutrition Formula One, which was manufactured between 1992 and 1994 as an all natural "nutritional supplement" containing plant ingredients, was actually made with two pharmaceutical-grade chemicals, ephedrine hydrochloride and caffeine anhydrous. FDA received more than 100 reports of injuries and adverse reactions related to the product and at least one death was associated with the use of this product. This case was developed by alerts provided from adverse event reports, ORA's field staff, and the work of OCI together with DOJ. Through these sources, FDA learned that the Chemins Company, Inc., which manufactured the product, went to great lengths to hide its actions from the Agency and concealed the actual ingredients of Formula One. As a result, the government initiated a criminal prosecution against the company and its president. On July 7, 2000, a Federal judge sentenced the president to 21 months in jail and fined him and this corporation \$4.7 million. In his plea agreement, the president admitted that he and his company labeled Formula One as "all natural but secretly spiked the product with synthetic ephedrine hydrochloride and caffeine anhydrous. He also admitted that the product's

labeling failed to disclose the use of the chemicals on the list of ingredients, and that he and his employees had misled FDA investigators and hindered inspections of Chemins. The sentence marked the culmination of a three-year investigation.

Joint Enforcement Actions

- On June 19, 2003, in an action initiated by FDA, U.S. Marshals seized \$2.6 million worth of Coral Calcium Supreme. In a separate action, FTC charged the marketers of Coral Calcium Supreme with making false and unsubstantiated claims that the product can treat or cure diseases such as cancer, multiple sclerosis, lupus, and heart disease. Stipulated preliminary injunctions have been entered against Trudeau, Barefoot, Shop America, LLC, and Deonna Enterprises, Inc. The preliminary injunctions prohibit the challenged claims and restrict defendants' ability to use or dissipate their assets. Legal proceedings are ongoing.
- On June 17, 2003, U.S. Marshals seized 132,480 bottles of Seasilver, worth nearly \$5.3 million, from Seasilver USA's San Diego, California, headquarters in an action initiated by FDA.. The complaint for seizure alleged that, although Seasilver USA marketed Seasilver as a dietary supplement, it promoted it on the Internet and in marketing materials sent with the product as a treatment for serious diseases including cancer, diabetes, hypoglycemia, psoriasis, hepatitis, and arthritis. On June 25, 2003, U.S. Marshals seized an additional 1.7 million dollars worth of Seasilver from a distribution center in Parma, Ohio. In response to an FTC request, the Federal district court in the Southern District of California issued a temporary restraining order on June 13, 2003,

prohibiting Seasilver USA, Americaloe Inc., and principals in the companies from making the challenged claims, and froze their assets. FTC is seeking preliminary and permanent injunctive relief, including restitution to consumers who purchased the product. Legal proceedings are ongoing.

- On May 27, 2003, the FTC filed a complaint against an individual and four of his corporations for making false and unsubstantiated claims. The individual claimed that five of the products marketed by him and his corporations as dietary supplements were "scientific breakthroughs" to treat or cure numerous serious medical conditions. FDA provided technical assistance and scientific support to FTC for this action. Products identified in the complaint included: Lung Support Formula (claimed to cure or ameliorate asthma, emphysema, smoking damage and other respiratory problems); Antibetic Pancreas Tonic (claimed to treat or cure diabetes and to lower blood sugar levels); GH3 and GH3 Romanian Youth Formula (claimed to extend life and prevent or treat Alzheimer's disease and other forms of dementia); Chitoplex (to promote weight loss and m obesity without diet or exercise); and Testerex (claimed to treat erectile dysfunction).
- On May 9, 2003, FDA and FTC warned website operators, manufacturers, and distributors to remove misleading or deceptive claims on the Internet that their products may prevent, treat or cure Severe Acute Respiratory Syndrome (SARS). A net "surf" conducted by FTC, FDA, and the Ontario Consumer and Business Services, found over 40 sites promoting a variety of SARS treatment and/or prevention products. The products included ingredients such as colloidal silver, ascorbic acid, beta glucan, pycnognsol, and oregano oil.

FDA sent Warning letters to eight firms promoting dietary supplement products as treatment or preventative remedies for SARS over the Internet. FTC also notified violative firms that they were subject to possible civil or criminal actions under the Federal Trade Commission Act. FDA has conducted appropriate follow-up to ensure that the firms have taken appropriate corrective action.

- In World Without Cancer Inc., FDA and DOJ, with the assistance of FTC, sought a temporary restraining order, preliminary injunction, and permanent injunction against the marketing of unapproved new drugs by three corporations and one individual. The products, laetrile, in both injectable and tablet forms, and apricot seeds, were promoted as "dietary supplement" cancer treatments through the firm's websites. The preliminary injunction and the subsequent Consent Decree of Permanent Injunction required the defendants to cease using the websites to promote the sale of offer for sale their laetrile products.